Z.ONE

Z.ONE ULTRASOUND SYSTEM : (2.0)

OPERATOR MANUAL

premium compact performance

Zone Sonography Technology

Z.ONE

BREAK THROUGH THE SOUND BARRIER.

ZONARE

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1

Introduction to the ZONARE z.one

The ZONARE **z.one** is the world's first Convertible Ultrasound™ system, easily converting from a full-featured SuperCart (or *mini*Cart) to a portable Scan Engine. This flexibility gives the clinician a software-controlled all-digital ultrasound system using Zone Sonography™ technology.

The **z.one** acquires and displays Brightness Mode (B-mode), Motion Mode (M-mode), Color Doppler, Power Doppler, and Pulsed Wave (PW) Doppler diagnostic images. Features include Sound Speed Compensation and Auto DGC (option), cine review, image zoom, real time triplex, annotation and body patterns, measurements and calculations, image archive and review, DICOM connectivity (option), image retrospective processing, printing, and recording capabilities. Images are stored on internal flash memory or exported to network-attached devices. Presets, selected by the exam type, make operation convenient and efficient.

The software-controlled architecture of Zone Sonography™ provides major advantages: compact premium performance; reduced cost of ownership; simple software upgrades; and more comprehensive Channel Domain™ image data used to form images.

The **z.one** easily converts from the full-featured SuperCart (or *mini*Cart) to the portable Scan Engine. This configuration gives the clinician the flexibility to acquire the same premium quality ultrasound images in a conventional cart-based configuration or a small compact unit, depending on the requirements of the clinical workflow.

The prudent use of ultrasound requires a constant consideration of the risk-benefit ratio for the patient, along with employment of the ALARA principle. ALARA is an acronym for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at a power output that is

"As Low As Reasonably Achievable." Before using the **z.one**, refer to "ALARA Principle" on page 9-9.

Intended Use

The **z.one** is the world's first Convertible Ultrasound™, instantly converting from the full-featured SuperCart (or *mini*Cart) to the portable Scan Engine. This flexibility gives the clinician a diagnostic ultrasound imaging system that is intended to be used for the following types of sonographic examinations:

- Obstetrics
- Gynecology
- Abdomen
- Neonatal / Pediatrics
- Small parts and superficial structures
- Vascular, peripheral and deep
- Needle guided procedures

z.one Components

SuperCart

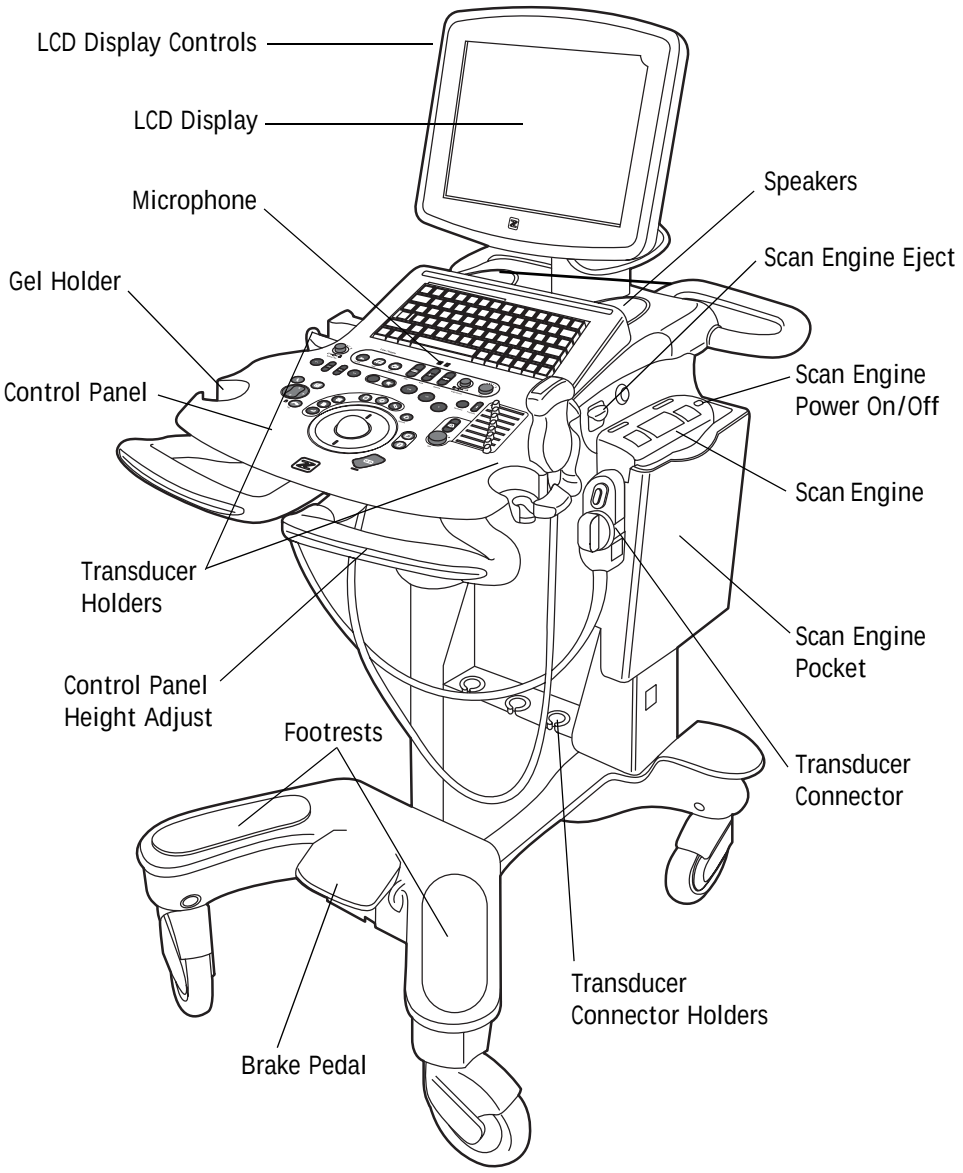


Figure 1-1. **SuperCart with Scan Engine Docked (Front View)**

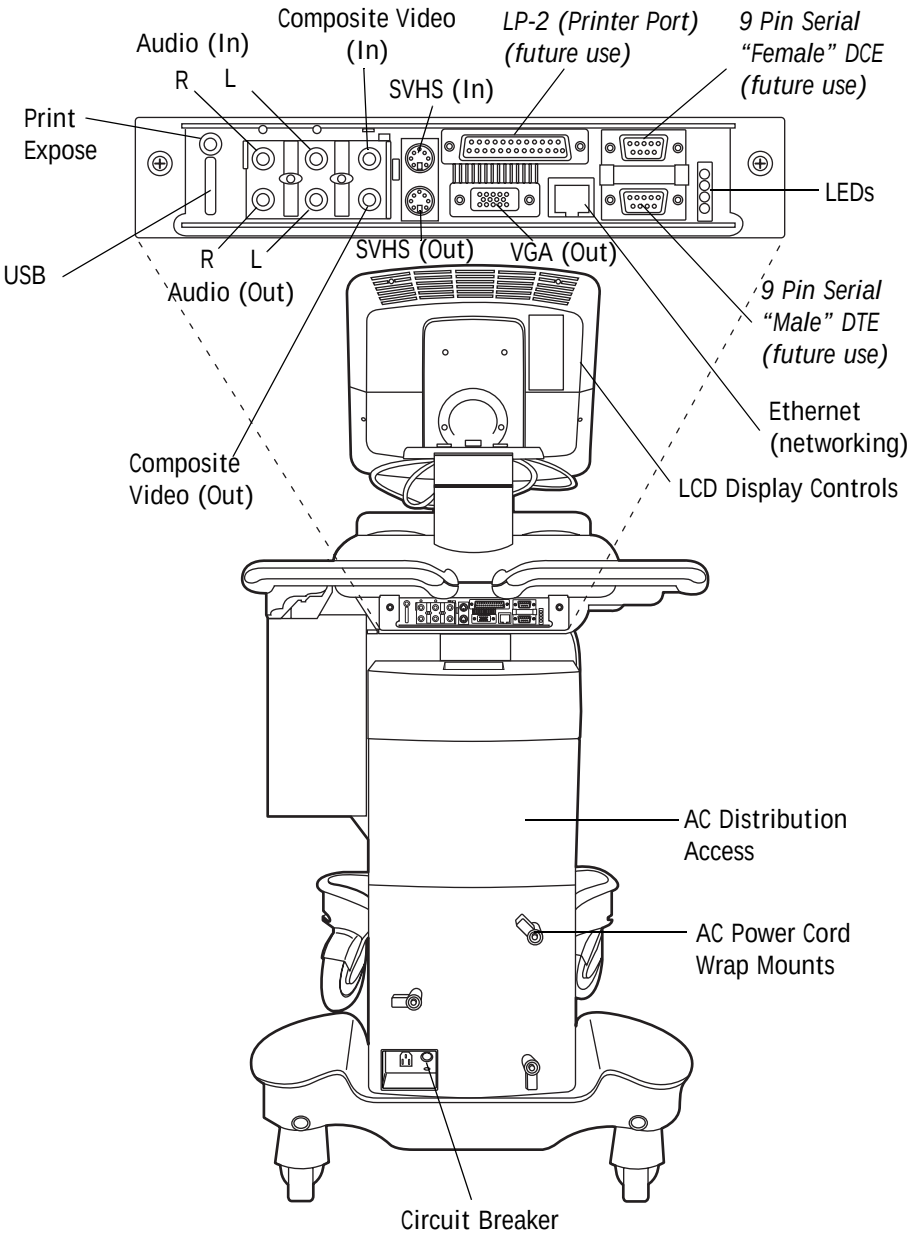


Figure 1-2. **SuperCart with Scan Engine Docked (Back View)**

The SuperCart is a full-function ultrasound workstation with a 13-inch LCD Display, a full-featured control panel, transducer storage, and peripheral and DICOM connectivity. It is smaller and lighter than conventional systems of equivalent image quality, and therefore can be used in situations where a conventional ultrasound system simply would not fit.

The Scan Engine serves as the main processing device ("brains") for the SuperCart. For the SuperCart to function, the Scan Engine must be docked (placed on the docking plate of the SuperCart). Refer to Figure 1-1. When the

Scan Engine is docked, the user can acquire images and carry out retrospective processing (gain adjustment, sweep speed, etc.) using the full-featured control panel. Patient images can be archived (saved) to the internal flash memory; and if ethernet connectivity is enabled, images can be saved to the network (DICOM) archive device. Images archived to internal flash memory can later be recalled for post-study analysis. The user can annotate images and perform basic measurements.

Scan Engine Docking

The Scan Engine pocket, in the SuperCart, is the docking station for the Scan Engine. It houses the electronic connections between the two **z.one** components. When the Scan Engine is docked and the SuperCart main circuit breaker is powered on, the Scan Engine's battery is being recharged.

The Scan Engine is the main processing component of the **z.one**. The push button power-on / off switch, on the Scan Engine (when the Scan Engine is docked in the pocket of the SuperCart), serves as the normal power on / off user control for the **z.one**. The circuit breaker, located at the rear of the SuperCart, is normally left in the "On" (up) position at all times (unless the SuperCart is being prepared for transport or service).

SuperCart LCD Display

Figure 1-3. **SuperCart LCD Display**

The SuperCart has a 13-inch LCD Display, which shows a full-screen view of the ultrasound image, plus patient and imaging information in designated areas of the screen. The brightness and contrast settings for the LCD Display on the SuperCart are adjustable by the user, using the rotary dials located on the left side of the LCD Display. Refer to Figure 1-8. When an on-screen setup menu is called up by exercising one of the LCD Display control dials, a corresponding menu appears briefly in the Control area on the left of the screen.

The LCD display controls include the following:

- Top dial: Controls brightness.
- Middle dial: Controls contrast.
- Bottom dial-push button: Displays a full menu control of monitor settings (for use by ZONARE service personnel only).

NOTE: For the top and middle dials, the recommended (factory default) settings are indicated by an ✱ next to the numeric value on the progress bar.

SuperCart Control Panel

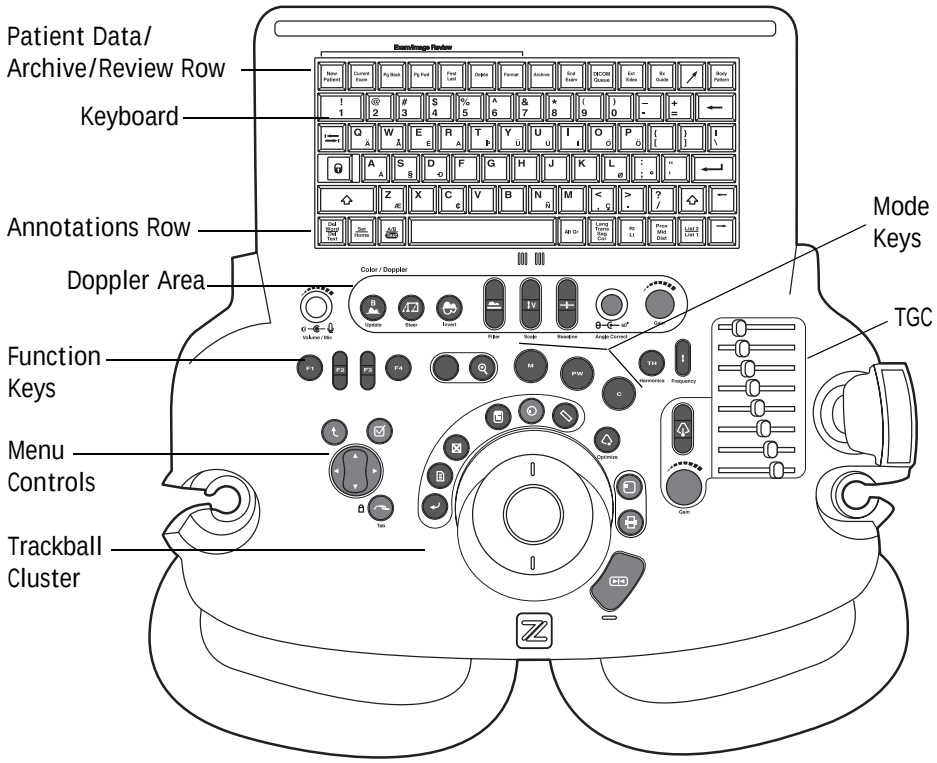


Figure 1-4. **SuperCart Control Panel: Overview**

The SuperCart control panel features include the following:

- The keyboard for annotating. This keyboard has additional control keys in the top and bottom rows for accessing image annotation, archive and review, and other special functions.
- The trackball and associated keys, used to position the cursors and to define the region of interest (ROI) and the Pulsed Wave (PW) gate in the image area.

- The Menu area, containing the **Menu Control** and keys for navigating menus.
- The Doppler area, with controls for optimizing color, power, and pulse wave Doppler images.
- The Mode keys, for entering and exiting M-mode, Color Doppler mode, and PW Doppler mode.
- The 2D control area with toggle/rocker keys, knobs, and Tissue Gain Compensation (TGC) for image optimization.

AC Distribution

The AC Distribution area, at the rear of the SuperCart, houses the I/O cables for the peripherals, an AC accessory outlet box, and the main circuit breaker for the SuperCart.

Transducer storage

Safe storage for approved **z.one** transducers is provided on both sides of the SuperCart.

*mini*Cart

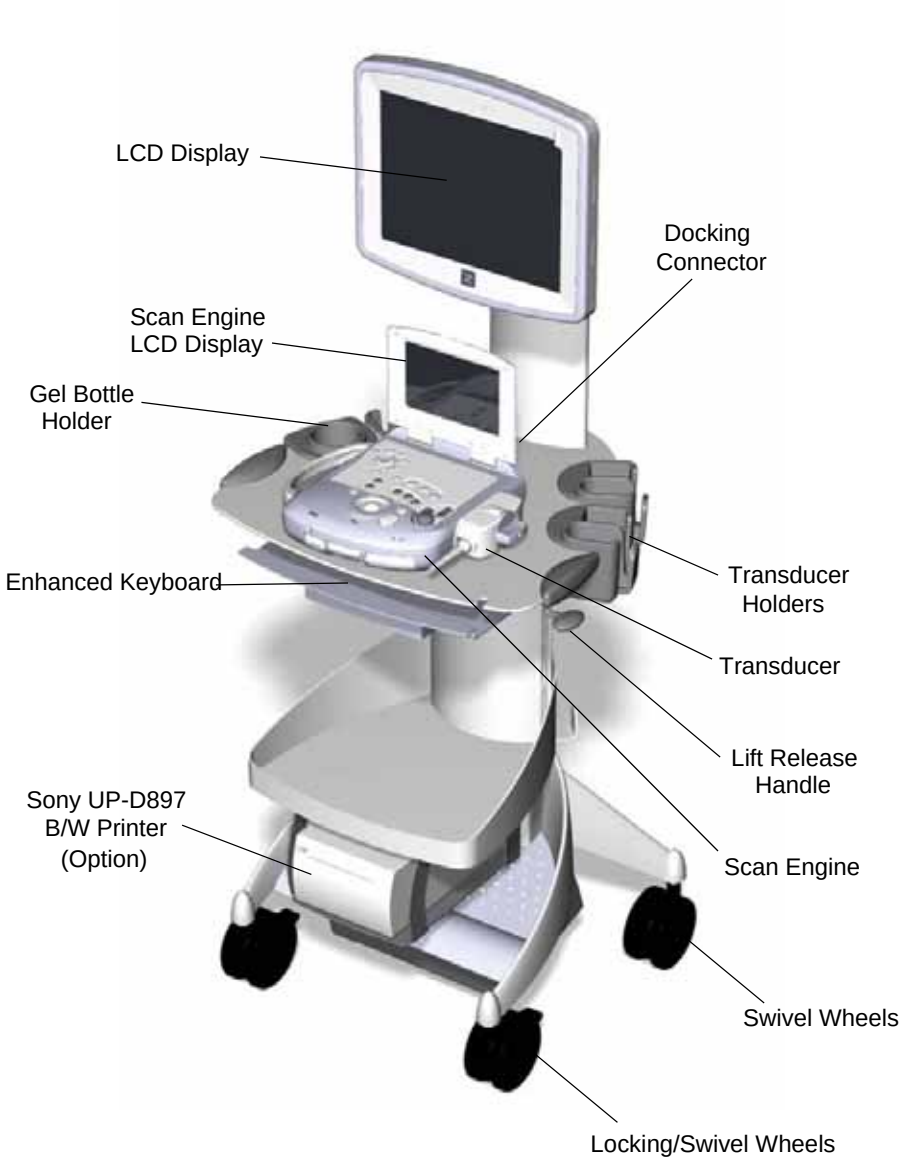


Figure 1-5. ***mini*Cart with Scan Engine Docked (Front View)**

The *mini*Cart is a compact ultrasound workstation with a 13-inch LCD Display, full-sized enhanced keyboard, transducer storage, and USB ports to support peripheral devices and networking (via a USB-to-Ethernet dongle). The *mini*Cart is smaller and lighter than conventional ultrasound systems of equivalent image quality, and therefore can be used in situations where a conventional ultrasound system simply would not fit.

The Scan Engine serves as the main processing device (“brains”) for the *mini*Cart. For the *mini*Cart to function, the Scan Engine must be docked (placed on the docking plate of the *mini*Cart). Refer to Figure 1-1. Patient images can be archived (saved) to the internal flash memory; and if ethernet connectivity is enabled, images can be saved to the network (DICOM) archive device. Images archived to internal flash memory can later be recalled for post-study analysis. The user can annotate images and perform basic measurements.

Patient images can also be imported or exported to / from the internal CompactFlash memory of the Scan Engine, utilizing a USB Flash Stick device. The USB Flash Memory device can be plugged directly into the USB port of the standalone Scan Engine, or into one of the USB ports on the *mini*Cart (when the Scan Engine is docked).

Scan Engine Docking

The Scan Engine pallet, on the *mini*Cart, is the docking station for the Scan Engine. It houses the electronic connections between the two z.one components. When the Scan Engine is docked and the *mini*Cart is powered on, the Scan Engine's battery is being recharged.

The Scan Engine is the main processing component of the z.one. The push button power-on / off switch, on the Scan Engine serves as the normal power on / off user control for the z.one.

miniCart LCD Display - Video Level Adjustment

Figure 1-6. ***mini*Cart LCD Display**

The *mini*Cart has a 13-inch LCD Display, which shows a full-screen view of the ultrasound image, plus patient and imaging information in designated areas of the screen.

Unlike the SuperCart, the LCD Display on the *mini*Cart does not have any manual adjustment control knobs. All adjustments of the LCD Display on the *mini*Cart are performed from an on-screen setup menu on the **z.one**.

The available adjustments are:

- Brightness
- Contrast
- Color Temperature (Red, Green, Blue)

The adjustment of the video settings on the LCD Display, are accomplished by performing the following steps.

1. Power on the **z.one** and allow it to fully boot.
2. Select **Tools | System Setup | Display** | **Audio/Video**|, to access the audio/video configuration menu.

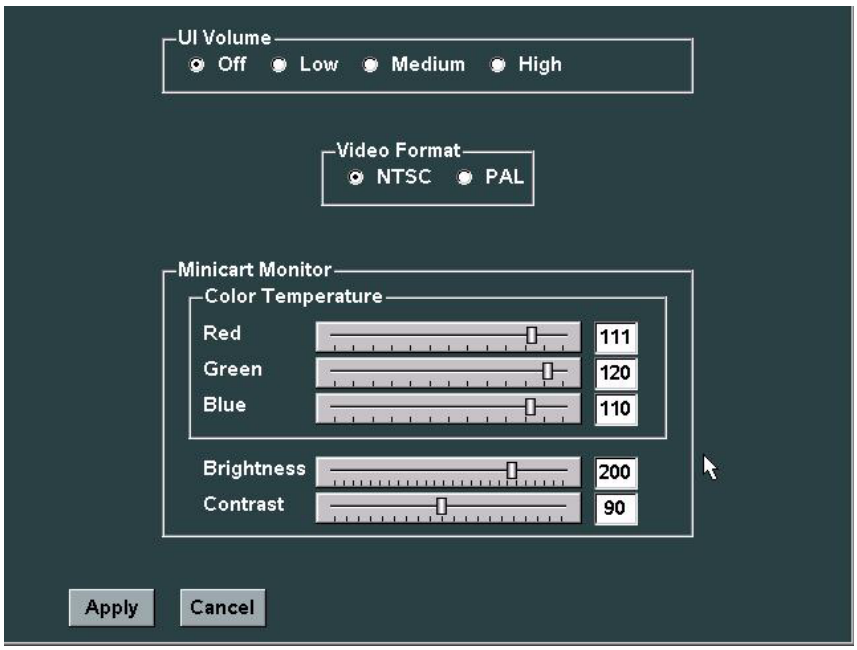


Figure 1-7. **Audio/Video Configuration Screen (*mini*Cart)**

3. Using the trackball, place the cursor arrow to the desired position on the sliding bar scale (of the desired display control), and press the **Set** key to mark the setting.

4. Repeat the steps above for any additional display settings that are desired for change.
5. To save the new settings and exit, select **Apply** from the menu, to save the configuration and return to the Audio/Video menu.
6. Visually inspect the output of the LCD Display, to confirm the desired video levels are achieved. Repeat the above steps, if required.

Cart Scan Engine Display Backstop

Figure 1-8. ***mini*Cart Scan Engine Display Backstop**

The *mini*Cart incorporates a custom display backstop that serves to hold the Scan Engine Touchscreen display in place while in use. Without the backstop, a user pushing on the Touchscreen display would soon find the display positioned in an undesirable use position.

The *mini*Cart backstop can slide up and down the *mini*Cart display column to allow the user to change the angle of the Scan Engine LCD display.

miniCart Controls

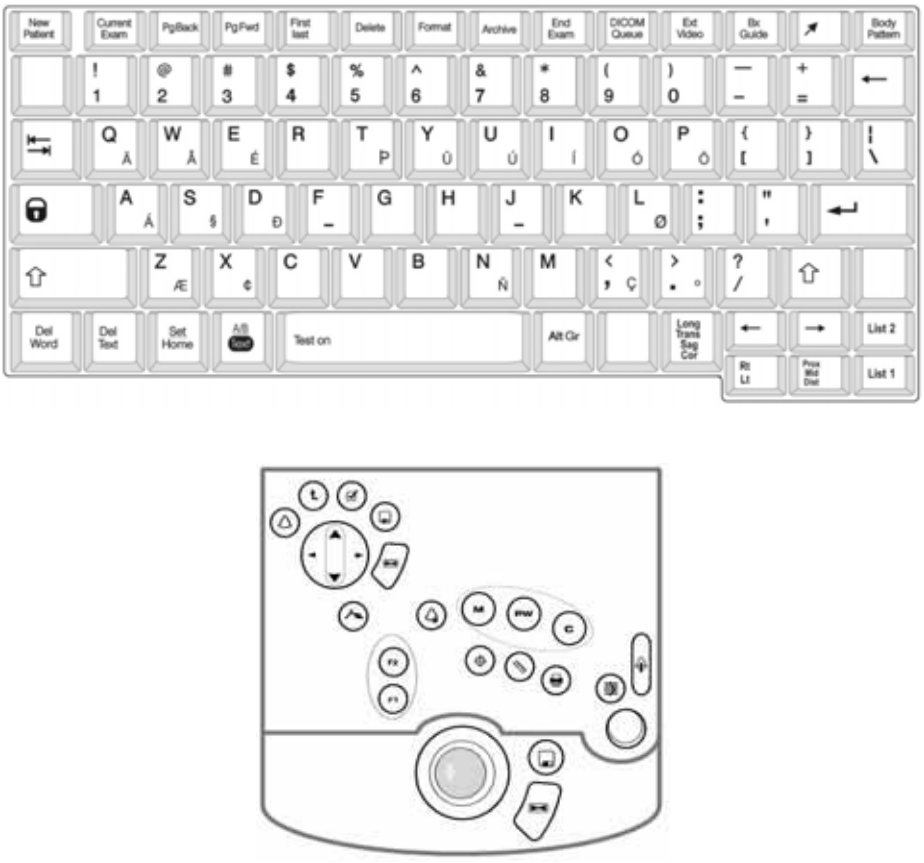


Figure 1-9. ***mini*Cart Enhanced Keyboard & Scan Engine Controls: Overview**

In the *mini*Cart configuration of the **z.one** system, mode selections, user menus and most basic operations are performed using trackball and buttons on the control panel of the Scan Engine. In addition to the control panel, the Scan Engine's flip-up display serves as a *touchscreen* for the user to quickly activate a number of the **z.one** system functions.

An enhanced keyboard is also included in the *mini*Cart configuration of the **z.one** system. The enhanced keyboard is located beneath the *mini*Cart's scanning pad, on a pull out shelf. The enhanced keyboard contains standard text keys for annotating, as well as dedicated function keys (in the top and bottom rows) for accessing image annotation, archive/review, and other special system operations.

AC Distribution

The *mini*Cart has an AC inlet and fuse holder. The *mini*Cart also contains an AC plug, available for use with the Sony UP-D897 Black & White Printer.

The only AC powered peripheral permitted to be used with the *mini*Cart supplied AC plug is the Sony UP-D897 B&W printer. Any other peripheral's usage would require that the user validate the usage to IEC60601.

Fuse Replacement:

Use T6.3A 250V slo-blow fuses when operating the *mini*Cart in a 100-120VAC environment. Use Littlefuse part number 021806.3HXP or equivalent.

Use T3.15A 250V slo-blow fuses when operating the *mini*Cart in a 200-220VAC environment. Use Littlefuse part number 02183.15HXP or equivalent.

miniCart Mobile Transport

To prevent potential damage to the *mini*Cart's LCD display monitor and mounting hardware, from shock and vibration that may occur during mobile transport (while loaded in a vehicle), a foam support pad should be placed between the bottom surface of the LCD display and the lily pad docking surface of the *mini*Cart

The combined height of the foam support should be tall enough to hold the LCD at a horizontal fold-down position (as shown below).

Figure 1-10. ***mini*Cart LCD Display Support (Mobile Transport)**

Transducer Storage

Safe storage for approved **z.one** transducers is provided on both sides of the *mini*Cart.

Scan Engine

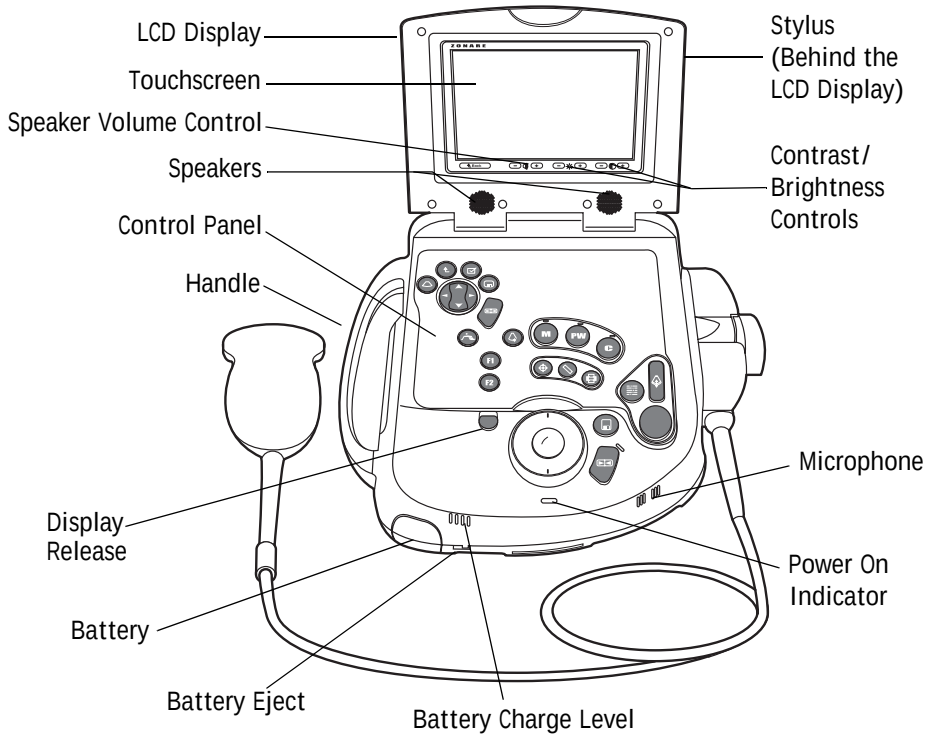


Figure 1-11. **Scan Engine with Transducer (Front View)**

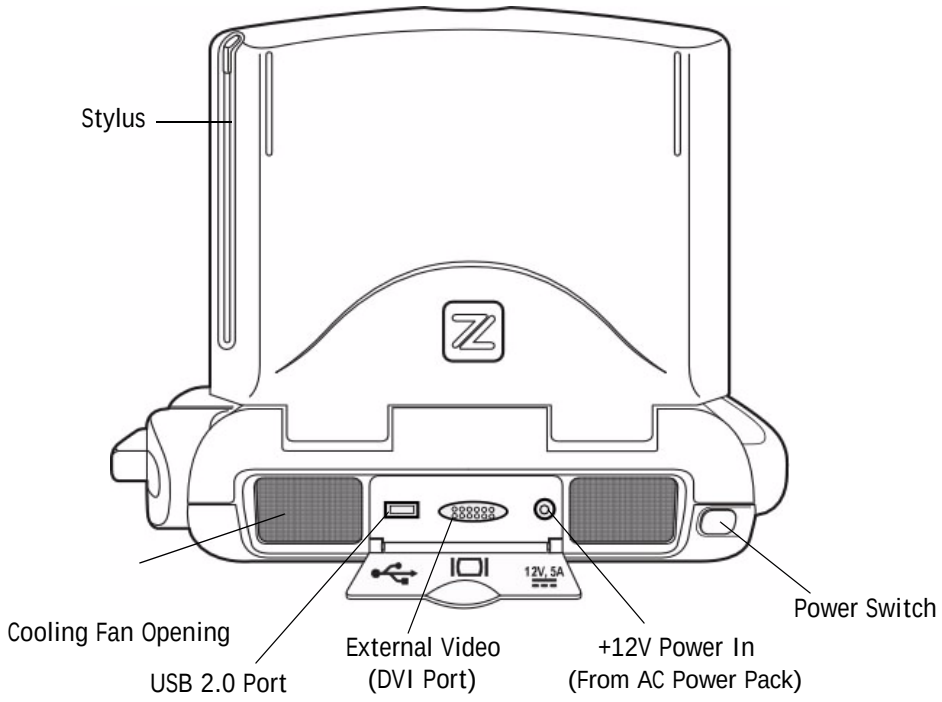


Figure 1-12. **Scan Engine (Back View)**

The Scan Engine contains the **z.one** system software. It can be used for complete examinations or limited procedures. When the Scan Engine is docked, images are processed internally using the 13” LCD Display on the SuperCart (or *mini*Cart). When the Scan Engine is undocked, images are displayed on the Scan Engine’s local LCD Display and user operations are performed on the Scan Engine’s local compact control panel.

The Scan Engine is powered by an internal rechargeable battery (or the optional AC adapter) when the Scan Engine is being operated in an undocked condition. The Scan Engine's internal battery is automatically being recharged anytime the Scan Engine is docked to an AC powered Supercart or *mini*Cart.

Scan Engine LCD Display

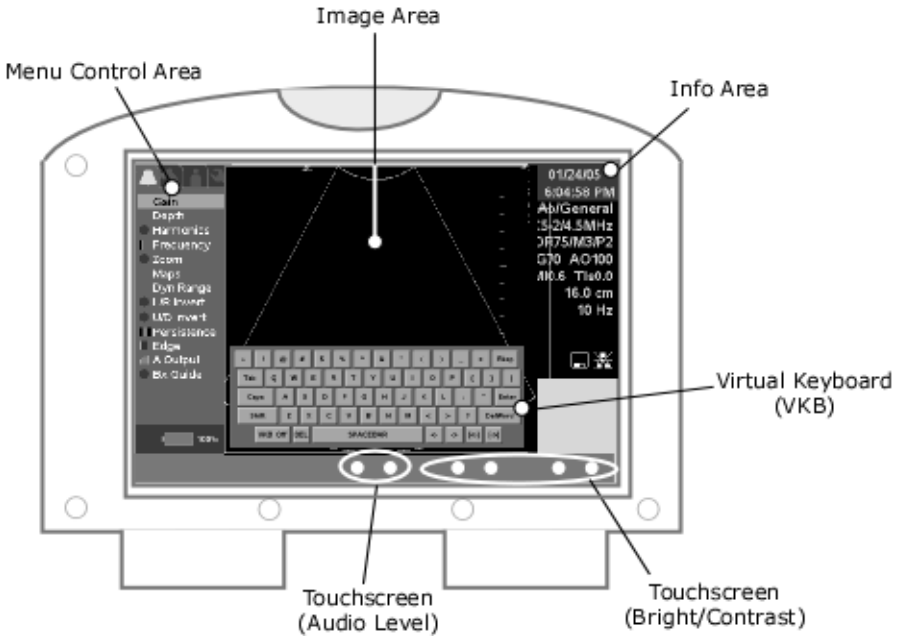


Figure 1-13. **Scan Engine LCD Display Layout**

The Scan Engine LCD Display is divided into the Image area in the center, the Control area on the left, and the Info area on the right. The Image area displays the sonogram, plus patient and image information in designated areas of the screen. Refer to Figure 1-13. The active on-screen menu displays in the Control area.

A touchscreen keyboard, called the Virtual Keyboard (VKB), can be displayed on the LCD Display of the Scan Engine. The VKB enables the user to make standard alpha-numeric data entries when the Scan Engine is being operated in an undocked condition from the SuperCart (or *mini*Cart).

The VKB is used for all functions requiring user data entry. Free-text annotations and other text / data entry operations (e.g., patient data entry and system configuration data entry) are inserted by touching virtual alphanumeric keys on the touchscreen, with the stylus.

The bezel surrounding the display includes additional touchscreen functionality. These functions include adjustments for brightness and contrast of the Scan Engine's LCD Display, and local speaker audio volume.

USB Memory Sticks

Figure 1-14. **USB Memory Sticks**

The **z.one** uses removable USB Memory sticks as the method for storage of patient image files and user Preset and user System configuration files. In addition, a USB Memory Stick is used as the source media for installing / upgrading system software on the Scan Engine.

There are two USB Memory Sticks that supplied at the time of system installation, which should be maintained at each system site. It is recommended that each USB Memory Stick ONLY be used for its own dedicated purpose (i.e. not storing patient images on the system / preset backup USB Memory Stick). The dedicated USB Memory Sticks that should be maintained at each **z.one** customer site are:

- 1) **Software Installer & User Presets/System Backup**
- 2) **Patient Image Archive**

WARNING: The USB Memory Sticks supplied by ZONARE are the recommended brand, type and sizes for use in the **z.one**. These USB Memory Sticks have been tested and verified for optimum reliability and performance. If the User outsources their own brand and size of USB Memory Stick, ZONARE is not responsible for any errors associated with file corruption, or file transfer time increases.

Transducers

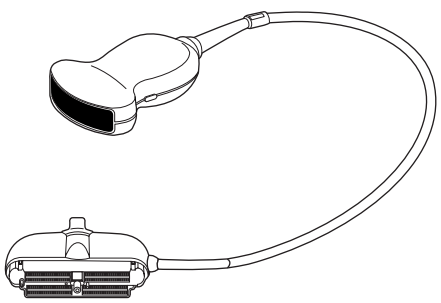


Figure 1-15. **Transducer**

The **z.one** transducers are lightweight and have a number of ergonomic features to maximize the ease of use for the user. These features include tactile orientation markers and grip ridges. Transducer holders on both sides of the SuperCart (or *mini*Cart) provide safe and accessible storage. Refer to "To connect a z.one transducer" on page 2-19.

Table 1-1.

Transducer	Exam Type	Biopsy Guide
C5–2	Abdominal	Yes
	Abdominal Vascular	
	Obstetrics	
	Fetal Heart	
	Gynecology	
E9–4	Obstetrics	Yes
	Gynecology	
L8-3	Peripheral Vascular	Yes
	Pediatric Hips	
	Difficult Small Parts	
L10-5	Thyroid	Yes
	Breast	
	Scrotum	
	Pediatric Hips	
	Small Parts	
	Peripheral Vascular	
P4-1	Deep Abdominal	*To be released*
	Trauma	
	Abdominal Vascular	
	Obstetrics	
	Fetal Heart	
	Gynecology	
P10-4	Neonatal	*To be released*
	Pediatric Head - Abdomen	
	Vascular	
	Intraoperative	

The **z.one** transducers have a specific range of acceptable application of use. ZONARE recommends that each transducer's use be restricted exclusively to those applications.

SuperCart Peripherals

ZONARE offers a number of optional medical grade (conform to the requirements of IEC 60601-1) peripherals. The peripherals currently offered for the SuperCart consist of the following:

- Sony UP-897MD B&W Thermal Video Printer
- Sony UP-21MD Color Thermal Video Printer
- Panasonic LQ-MD800 DVD Video Recorder

Instructions for proper use of each peripheral are covered in the manufacturer's instructions for use documents.

*mini*Cart Peripherals

ZONARE offers an optional medical grade (conforms to the requirements of IEC 60601-1) peripheral. The only peripheral device currently offered for the *mini*Cart consists of the following:

- Sony UP-D897 B&W USB Digital Printer

Instructions for proper use of peripherals are covered in the manufacturer's "Instructions For Use" documents.

DICOM Connectivity

DICOM connectivity is an *optional* software feature on the **z.one**. When activated and configured, DICOM connectivity enables the medical image and associated patient and exam data to be transmitted over the institution's network. The connectivity provided by DICOM enhances the efficiency of the storage and output of medical imaging data. Refer to DICOM store and print information in "DICOM Connectivity" on page 8-1 for more information. When DICOM is activated and configured, DICOM Store, DICOM Print, and DICOM Worklist functions may be enabled.

Contact and System Information

If you have any questions, see ZONARE's Web site at www.zonare.com.

ZONARE Medical Systems Inc.
1061 Terra Bella Avenue
Mountain View, CA 94043-1839

To contact Tech Support, call: 650-316-3199

For other contact numbers, refer to “Contact Information for ZONARE Service and Technical Support” on page 11-1.

2

Getting Started

SuperCart & *mini*Cart Moving Cautions

Introduction

The information in this section is intended to provide recommendations and cautions for the user to follow when moving (rolling) the SuperCart or *mini*Cart over a variety of possible surfaces.

To move the SuperCart or *mini*Cart

NOTE: ALWAYS follow these precautions when moving the SuperCart or *mini*Cart.

1. Lower the adjustable height to MINIMUM.

CAUTION: To maximize the stability of the SuperCart or *mini*Cart during movement across irregular surfaces, the user should use the release lever to adjust the height of the User Interface/LCD Display assembly to its **LOWEST** possible position, PRIOR to relocation of the unit.

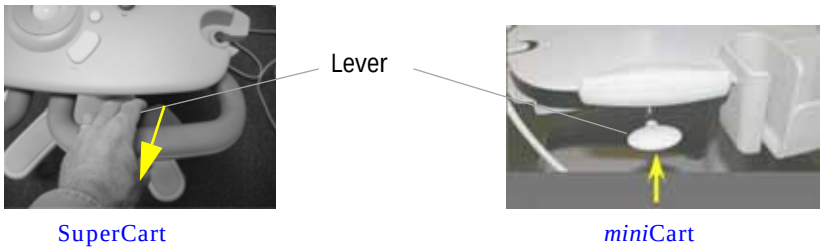


Figure 2-1. **Height Release Lever Positioning (SuperCart & *mini*Cart)**

2. Fold the LCD Display down to a horizontal position.

CAUTION: To prevent possible damage to the LCD Display on the SuperCart or *mini*Cart, during transport of the unit, always rotate the LCD Display to the facing-forward position and then fold it downward into a horizontal position (as shown in Figure 2-2).

NO

YES

Figure 2-2. **LCD Display Position**

3. Ensure that the transducer cables are wrapped over the cable hooks.

CAUTION: To prevent possible damage to the cables of the transducers, from the wheels of the SuperCart or *mini*Cart during movement of the unit, ensure that they are wrapped over the cable hooks (provided at the front of the system) such that they are suspended above the floor (as shown in Figure 2-3).

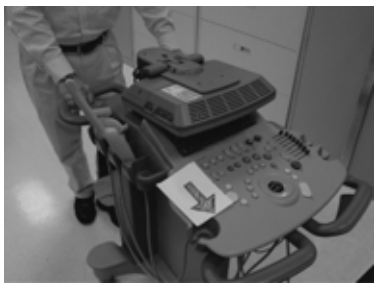
YES

YES

Figure 2-3. **Do's for Transducer Cables**

4. For movement over normal smooth surfaces, push the SuperCart or *mini*Cart from the rear handle(s), with the pivoting front wheels leading.

CAUTION: To ensure maximum maneuverability and stability (to prevent potential tipping) of the SuperCart, when moving the SuperCart over normal smooth surfaces it should be pushed with the pivoting wheels leading, and the fixed wheels trailing.



YES

Figure 2-4. **User Position During Normal Cart Movement**

5. When moving the SuperCart or *mini*Cart over obstacles, always ***pull*** the Cart from the front (or back); do not push.

CAUTION: To prevent possible tipping of the SuperCart or *mini*Cart, anytime it is being moved over a surface that has an elevation change (doorway lip, pavement seam, etc.), the user must ensure that the Cart is ***pulled*** across (the operator leading the Cart over the obstacle), rather than pushed.

NO

YES

Figure 2-5. **Cart Wheel Position over Obstacles**

NO

YES

Figure 2-6. **User Position During Cart Movement over Obstacles**

Security Locking of the Scan Engine

To ensure the security of the Scan Engine (from possible theft, etc), a removable key locking mechanism is provided on the **z.one**. The key lock will enable / disable the removal of the Scan Engine from the pocket of the SuperCart, or the *lily pad* on the *mini*Cart.

The key lock is located, as shown in the pictures below.

SuperCart Key Lock

*mini*Cart Key Lock

Figure 2-7. **Scan Engine Security "Locking" in SuperCart or *mini*Cart**

Docking and Undocking the Scan Engine

To ensure the security of the Scan Engine (from possible theft, etc), a To work with either the SuperCart or the *mini*Cart, the Scan Engine must be docked. The docking two mechanisms are quite different; this section will describe the docking mechanism of the two

All imaging functions are available on the Scan Engine when it is undocked from either the SuperCart or the *mini*Cart.

To dock the Scan Engine in the SuperCart

Hold the Scan Engine with the front panel facing down into the Scan Engine pocket on the SuperCart. Line up the track on the bottom surface of pocket with the tracks on the bottom of the Scan Engine. Gently push it into place until a positive "click" is heard.

Figure 2-8. **Scan Engine Docking in SuperCart**

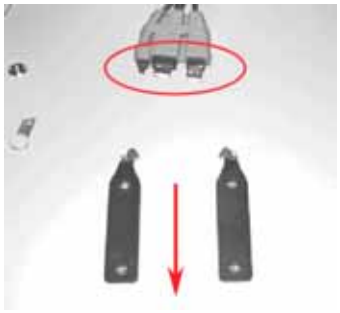
To undock the Scan Engine from the SuperCart

Press the ejection latch above the Scan Engine pocket. The Scan Engine is ejected partially out of the pocket. Grasp and remove the Scan Engine.

To dock the Scan Engine on the *mini*Cart

Hold the Scan Engine centered (horizontally) and rearward above the *lily pad* on the *mini*Cart. Line up the tracks on the top surface of *lily pad* with the tracks on the bottom of the Scan Engine. While resting flat on the *lily pad* surface, gently slide the scan engine directly towards you (forward), to engage it on the docking latches. Continue to slide the Scan Engine towards you, until a positive audible "click" is heard.

Open the I/O access door at the rear of the Scan Engine, and connect the docking connector cable assembly to the mating connectors on the Scan Engine.



Lily Pad & Docking Connector

Scan Engine Docking “IN”

Figure 2-9. **Scan Engine Docking in *mini*Cart**

To undock the Scan Engine from the *mini*Cart

Disconnect the docking connector cable assembly from the mating connectors on the rear of the Scan Engine.

Figure 2-10. **Scan Engine Undocking from *mini*Cart**

Slide (press rearward) the ejection latch (located in the upper left corner of the *lily pad*), to release the Scan Engine from the *lily pad*. Grasp the Scan Engine and slide it away from you (rearward) to release it from the docking latches. Lift the Scan Engine to remove it from the *mini*Cart.

Powering On and Off

Please read and understand all Warnings and Cautions in "Warnings and Cautions" on page 9-3 before powering on the **z.one**.

Powering on the z.one

SuperCart:

1. Locate the circuit breaker (located at the left/rear of the SuperCart) on the SuperCart and move it to the On (up) position. Refer to Figure 2-11.

***mini*Cart:**

NOTE: The *mini*Cart does not have a separate power switch or circuit breaker

2. Locate the power button on the back left of the Scan Engine. Press the button. Refer to Figure 2-11.

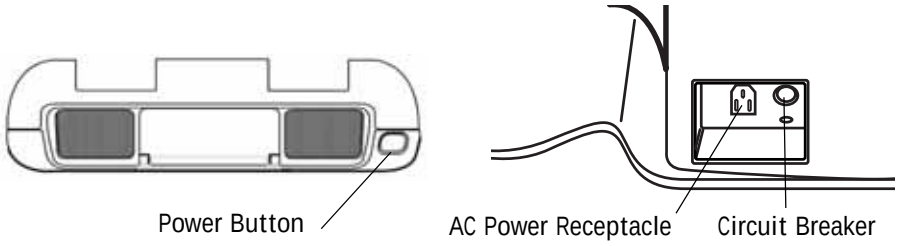


Figure 2-11. **Scan Engine Power Button and SuperCart Circuit Breaker**

3. The **z.one** will take approximately one minute to complete the normal power on sequence.

4. To verify successful power on, check the SuperCart display to ensure the following.

   The ZONARE start-up screen displays while the system is initializing. When initializing is complete, the system is ready for B-mode imaging.

Figure 2-12. **ZONARE Start-up Screen**

NOTE: If the start-up screen does not display, the system failed to power on. Completely eject the Scan Engine from the SuperCart pocket and visually inspect the Scan Engine. Reinsert the Scan Engine and try to power on. Refer to "Contact Information for ZONARE Service and Technical Support" on page 11-1.

Password Protection (Access Control)

Password protection can be enabled on the **z.one** to prevent unauthorized use of the system. The Access Control menu is used for configuring the log-on password.

CAUTION: If password protection (Access Control) is elected to be used to restrict access to the **z.one**, it is extremely important that the user-assigned password be retained in a safe place by the System Administrator.

If Access Control is configured by the User in this menu, and the user-assigned password is subsequently lost or forgotten; no master password is available for recovering access to the **z.one** for normal operation. A complete re-installation of system software will be required to regain normal use of the **z.one**.

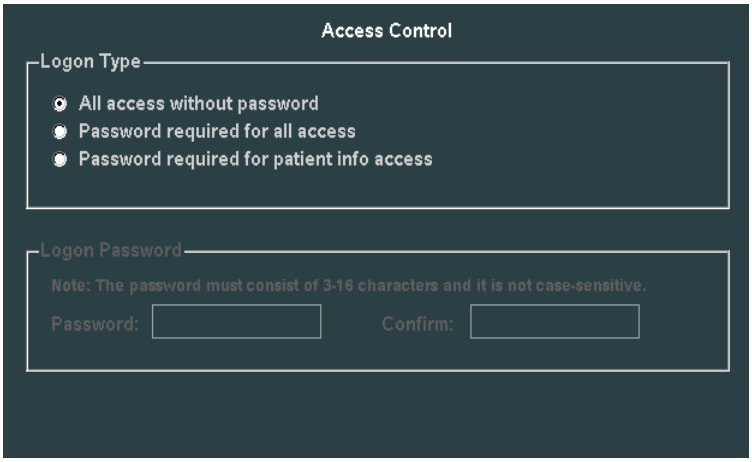

Access Control
Logon Type
All access without password
Password required for all access
Password required for patient info access
Logon Password
Note: The password must consist of 3-16 characters and it is not case-sensitive.
Password:
Confirm:

Figure 2-13. **Access Control Screen**

1. If password log-on has been configured, a log-on screen will appear. Enter the previously configured password to enable system operation.

2. To connect a transducer, refer to "To connect a z.one transducer" on page 2-20.

3. To install a USB Memory Stick, refer to "Inserting and Removing USB Memory Stick Media" on page 2-11.

   A USB Memory Stick icon is displayed on the right of the screen. If a USB Memory Stick is not installed, the icon is displayed with an **X** through it. Verify that the card has sufficient storage memory available to store exam images. To install a USB Memory Stick or check the available memory, refer to "Inserting and Removing USB Memory Stick Media" on page 2-11.

   If the screen is blank or is otherwise not the default display, check the transducer connections and, if necessary, reconnect the transducer. If a normal display is still not present, connect a different transducer. If the normal display is not present with the second transducer, power the system off and call Tech Support. Refer to "Contact Information for ZONARE Service and Technical Support" on page 11-1.

To power off the SuperCart

NOTE: Normally the SuperCart's main AC circuit breaker power is left on, even when the **z.one** has been shutdown from normal use (using the Scan Engine power on/off switch). However, any time the SuperCart is being moved the following SuperCart power off sequence should be followed.

1. Press the Scan Engine power button. The Scan Engine takes about 10 seconds to perform a normal shutdown sequence, and then powers off.

2. Move the SuperCart circuit breaker (located at the left/rear of the SuperCart) to the off (down) position.

To power on the Scan Engine (undocked)

1. Ensure that the Scan Engine battery is charged. Refer to "Installing and Removing a Battery" on page 2-12.

2. Locate the power button on the back of the Scan Engine, and press the button.

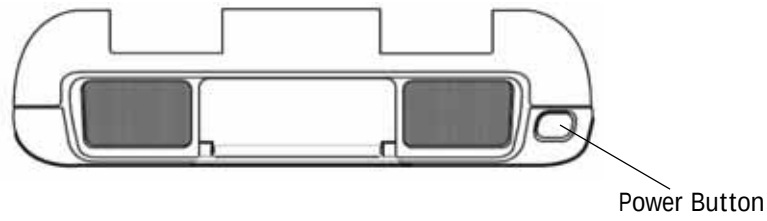


Figure 2-14. **Scan Engine Power Button**

3. To check the Scan Engine display, ensure the following:
   - The ZONARE start-up screen displays while the system is initializing. When initializing is complete, the system is ready for B-mode imaging.
   - If the screen is blank or is otherwise not the default display, check the transducer connections and reconnect the transducer. If a normal display is still not present, connect a different transducer. If the normal display is not present with the second transducer, power the system off and call Tech Support. Refer to "Contact Information for ZONARE Service and Technical Support" on page 11-1.
   - A USB Memory Stick icon displays on the right of the screen when a stick is installed. Verify that the stick has sufficient storage memory available to store exam images. To install USB Memory Stick media or check the available memory, refer to "Inserting and Removing USB Memory Stick Media" on page 2-11.

4. To log in to the **z.one,** enter the password in the Password data field. If password protection is enabled on the system, the log-on screen displays.

5. To connect a transducer, refer to "To connect a z.one transducer" on page 2-20.

6. To install a USB Memory Stick, refer to "Inserting and Removing USB Memory Stick Media" on page 2-11.

To power off the Scan Engine

Press the Scan Engine power button. The Scan Engine takes about 10 seconds to perform a normal shutdown sequence, and then powers off.

Inserting and Removing USB Memory Stick Media

The **z.one** utilizes removable USB Memory sticks for two (2) specific purposes.

- **Software Installer & User Preset - System Backup**
- **Patient Image Archive**

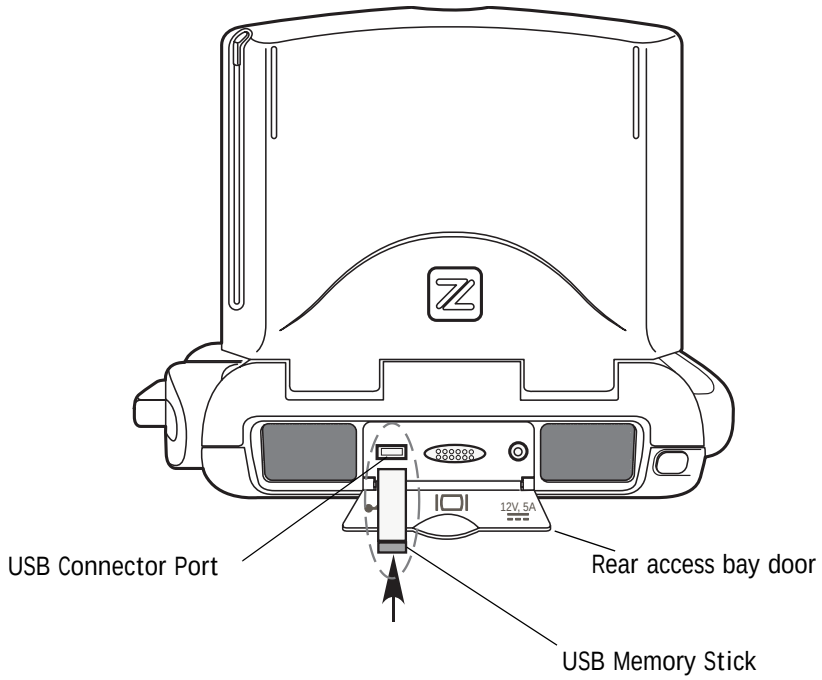


Figure 2-15. **USB Memory Stick and Scan Engine (Rear View)**

To install a USB Memory Stick

A USB Memory Stick can be installed while the **z.one** is powered on or off.

1. Open the rear bay door.
2. Position the USB Memory stick in front of the USB connector port of the Scan Engine.
3. To insert the USB Memory Stick, hold it with the proper orientation. Push the USB Memory Stick gently all the way into the USB port slot.

To remove a USB Memory Stick

CAUTION: It is important to ensure that the Scan Engine has fully completed accessing (writing/editing/deleting) data on USB Memory Stick, PRIOR to removing it from the Scan Engine. Failure to observe this caution, by ejecting the USB Memory Stick at any time that it is being accessed, will result in loss of data!

1. To eject the USB Memory Stick, firmly grasp the USB Memory Stick on either side with your fingers, and pull it out all the way.

Installing and Removing a Battery

Figure 2-16. **z.one Battery**

To install a battery

NOTE: Ensure that the Scan Engine has been removed from the SuperCart before installing/replacing the battery.

1. To verify the charge on the battery, refer to "Checking Battery Charge" on page 2-13.
2. To install the battery, locate the battery pocket on the left side of the Scan Engine. Line up the prominent groove on the battery with the corresponding tongue on the left inside surface of the battery pocket.

Push the battery in until it is fully seated and latched in place. The battery charge indicators (on the Scan Engine to the right of the battery pocket) light up.

To eject a battery

Push the battery release latch to the right of the battery pocket.

Checking Battery Charge

A charge indicator on the labeled surface of the battery has four LEDs lined up with four small holes in the label. To check the charge on a battery, press the circle to the left, which is the Charge Indicator test button.

Another charge indicator on the front panel of the Scan Engine has four LEDs that light up briefly when the battery is installed.

Charge remaining	Indicator
<25%	1 LED
25–49%	2 LEDs
50–74%	3 LEDs
≥75%	4 LEDs

The battery operating range is as follows:

Usage	Duration (approximate values)
Active use	30-60 Minutes (dependent on modes and display brightness)
Standby mode	2.0–3.0 hours
Storage mode (in Scan Engine)	3 weeks

When the Scan Engine is powered on, the percentage of battery charge remaining is displayed in the Status area of the screen. When the charge becomes low, the battery icon in the Status area changes color and on-screen messages display as follows:

Charge remaining	Indicator
<25%	Battery icon turns amber.
<5%	Battery icon flashes, followed by a system shutdown message.

Battery Thermal Protection

WARNING: To protect the **z.one** battery from potential thermal damage, the system monitors the temperature of the battery at all times. If the battery is detected as exceeding the maximum safe operating temperature, a warning message will appear on the display of the **z.one**.

The Operator should immediately complete all active operations, in preparation for the system automatically initiating a power-down sequence.

Battery Charger, 2-Bay: Connection & Use

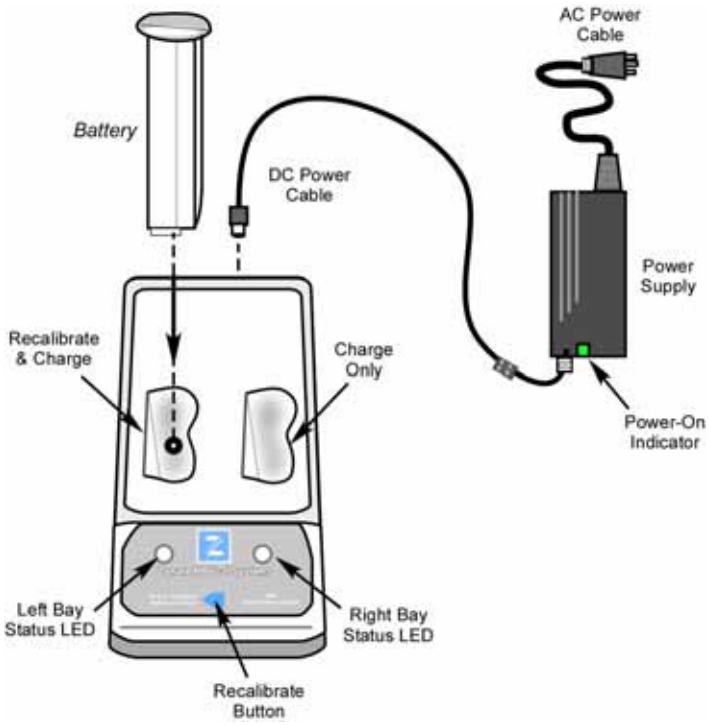


Figure 2-17. **Battery Charger, 2-Bay**

The battery pack inside the **z.one** Scan Engine is recharged during normal use, when the Scan Engine is docked in the SuperCart, and the SuperCart has AC power applied.

During standalone (undocked) operation, the Scan Engine will require replacement with a freshly charged battery pack after approximately 1 hour of continuous use. The 2-Bay Battery Charger should be used for maintaining the charge of spare battery packs, and occasional recalibrating (*reconditioning*), of the **z.one** battery packs to maximize their operational efficiency.

The two functions of the 2-Bay Battery Charger are:

- ""Charge" mode:The battery receives a single full charging cycle
- ""Recalibration" mode:The battery is discharged -> charged -> discharged again - final charged

Recalibrating (*Reconditioning*) a Battery Pack

1. Connect the AC power cable to an active wall outlet, and connect the DC power cable between the power supply and the 2-Bay Battery Charger

2. Insert the battery pack into the LEFT bay of the 2-Bay Battery Charger (Note: Only the LEFT bay performs "Recalibration")

3. Press the "Recalibrate" button on the 2-Bay Battery Charger

During the "Recalibrate" process, the left status LED flashes ORANGE. Once the "Recalibrate" process is completed, this same LED will intermittently flash between ORANGE and GREEN.

NOTE: The "Recalibrate" process may require 14 hours to fully complete

The battery pack should NOT be removed prior to completion of the "Recalibrate" process, as the battery will be at an unknown level of charge

Charging a Battery Pack

1. Connect the AC power cable to an active wall outlet, and connect the DC power cable between the power supply and the 2-Bay Battery Charger

2. Insert the battery pack into the EITHER bay of the 2-Bay Battery Charger

3. The charging cycle on the docked battery pack will automatically begin to execute

4. During the "Charging" process, the corresponding status LED flashes GREEN. Once the "Charging" process is completed, this same LED becomes solid GREEN.

NOTE: The "Charging" process, in the two bays of the unit, is performed in a "sequential" fashion. If two battery packs are docked into the 2-Bay Battery Charger at the same time, the charger will perform the complete charging sequence on one battery pack, before starting the charging sequence on the second battery

LED Status Indicators: Battery Charger

Status LED Condition	LED	Definition
OFF		No battery pack detected in bay
ORANGE – "Flashing"		"Recalibration" of battery pack in progress
ORANGE/GREEN – "Flashing"		"Recalibration" complete (fully charged)
GREEN – "Flashing"		"Charging" of battery pack in progress
GREEN - Solid		"Charging" of battery pack complete
ORANGE - Solid		"Standby" – Battery in bay, waiting to be charged
RED – "Flashing"		ERROR: - Ensure no foreign objects are in bays - Inspect battery pack for defective condition - Battery temp has exceeded 65°C (149°F)

Figure 2-18. **LED Status Indicator Definitions**

AC Power Adapter: Connection & Use

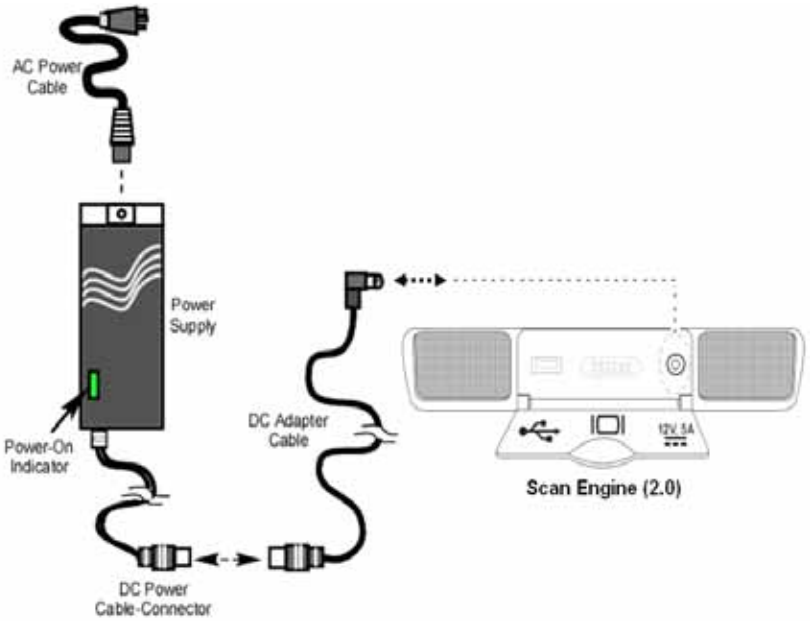


Figure 2-19. **AC Power Adapter - 2.0 Scan Engine**

For extended (more than 1 hour) standalone (undocked) use of the Scan Engine, the AC Power Adapter should be used. The AC Power Adapter is plugged into the +12VDC power connector, located inside the rear panel access door at the back of the Scan Engine.

To connect the AC Power Adapter

NOTE: Ensure that the Scan Engine has been removed from the SuperCart before using the AC Battery Pack

1. Power off the Scan Engine, and ensure it is being used remotely (ejected) from the SuperCart.
2. Connect the DC Power Cable to the +12VDC connector at the rear of the Scan Engine (located inside the rear access door).
3. Connect the output connector of the DC Power Cable (out of the Power Supply) to the DC Adapter Cable's mating connector
4. Plug the AC Power Cable's female connector into the socket on the Power Supply
5. Plug the other end of the AC Power Cable into an active AC wall outlet

6. Inspect the Power-On indicator lamp on the Power Supply, to ensure power is applied and the unit is on

7. Power on the Scan Engine and begin normal operation

Connecting and Disconnecting a Transducer

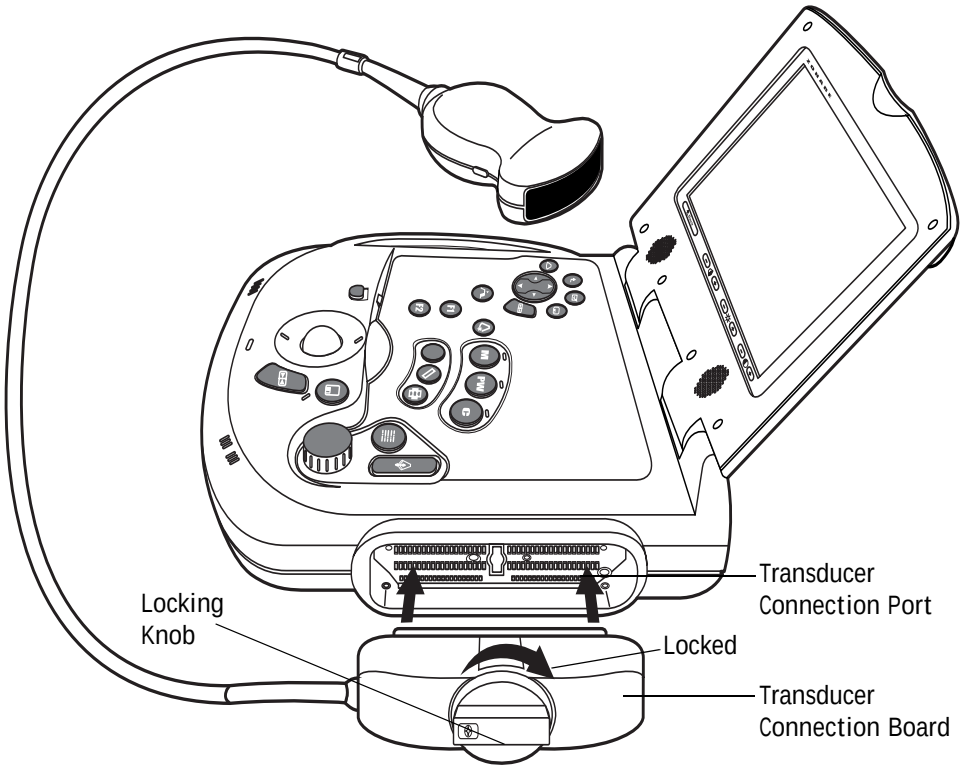


Figure 2-20. **z.one Transducer**

To connect a z.one transducer

A transducer can be connected or disconnected while the **z.one** is powered on or off.

1. Verify the integrity of the transducer and the connectors.

   WARNING: Before each use the transducer must be inspected to avoid risk of injury. Inspect the transducer face, housing, cable, connectors, and cases. Do not use the unit if damage is detected.

2. Insert the transducer's connector into the alignment hole on the Scan Engine's transducer connection board, and ensure it is fully seated.

3. Turn the locking knob on the transducer connector one quarter turn clockwise, to lock the transducer in place. Refer to Figure 2-20.

4. Verify a proper connection, by the presence of an initial *"initializing transducer"* message which should appear on the LCD Display. This also indicates that the transducer has been properly recognized by the **z.one**.

5. After approximately 10 seconds, the system should automatically begin actively operating the transducer in B-mode. A basic B-mode image should now be displayed in the Image area of the LCD Display.

To disconnect a z.one transducer

1. To disconnect the transducer from the Scan Engine, turn the locking knob one quarter turn counter clockwise and remove the transducer connector from the transducer connection port. Refer to Figure 2-20.

NOTE: A *"No transducer connected"* message should be displayed on the LCD Display.

2. To store the transducer, place it in the transducer connection holders on the SuperCart. Refer to Figure 1-1.

Applying a Transducer Cover

To apply a transducer cover

1. To prepare the cover, remove it from the packaging. Apply water-based ultrasound gel to the inside of the cover.

2. To place the cover on the transducer, pull the cover securely over the transducer and remove any wrinkles or air bubbles. Secure the cover to the transducer with plastic bands.

Attaching a Biopsy Guide

To attach a reusable (nondisposable) biopsy guide

1. To attach the biopsy guide to the transducer, refer to the biopsy guide product information.
2. To apply a sterile transducer cover, refer to "Applying a Transducer Cover" on page 2-21.
3. To attach a disposable sterile needle guide attachment to the biopsy guide, the transducer cover remains in place, and the needle guide is attached over it.
4. To activate the on-screen biopsy needle guide graphics, do the following:

   SuperCart: Press **Bx Guide** (top row of SuperCart keyboard keys).

   Scan Engine: Activate the Imaging tab. On the B-mode menu, select **Biopsy Guide**.

   The relative path of the needle (2 lines or more) displays on the sonogram. Refer to the biopsy-needle instructions enclosed with the biopsy guide.

To attach a disposable biopsy guide (EV exam only)

1. To apply a sterile transducer cover, refer to"Applying a Transducer Cover" on page 2-21.
2. To attach a sterile disposable biopsy guide, attach the biopsy guide over the transducer cover. A disposable biopsy guide is a needle and needle guide in one piece. Ensure that the biopsy guide is locked.
3. Apply another sterile transducer cover (optional).
4. To activate the on-screen biopsy needle guide graphics, do the following:

   SuperCart: Press **Bx Guide** (top row of SuperCart keyboard keys).

   Scan Engine: Activate the Imaging tab. On the B-mode menu, select **Biopsy Guide**.

   The relative path of the needle (2 lines or more) displays on the sonogram. Refer to the biopsy-needle instructions enclosed with the biopsy guide.

Mechanical Controls

Brakes **SuperCart:** The brake mechanism of the SuperCart allows the user to lock rotation and swivel (in 90-degree increments) of the front wheels, to prevent

undesired movement during system operation. Pressing downward fully on the brake pedal will lock the front wheels on the SuperCart from rolling. In addition, the front wheels may be rotated to a 90-degree angle prior to locking the brake, if desired, to provide additional stability during shipping. Pressing the brake pedal downward a second time will release the wheels.

Figure 2-21. **Brake Pedal (SuperCart)**

***mini*Cart:** The brake mechanism of the *mini*Cart allows the user to lock rotation (brake) of the front wheels, to prevent undesired movement during system operation. Pressing "Down" fully on the brake lever, on each of the two front wheels, will lock them from rolling. Lifting "Up" on each of the brake levers, will release the wheels.

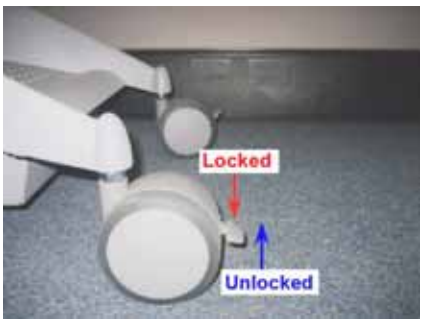


Figure 2-22. **Brake Levers (*mini*Cart)**

Height adjustment

The **z.one** SuperCart and *mini*Cart include a hydraulic lift mechanism that enables the user to optimize the vertical position (height) of the user interface panel and LCD Display for optimum comfort and viewing during operation.

SuperCart: Pull *inward* on the release lever, located on the inside of the right-front handle assembly on the SuperCart, allows the height of the SuperCart to be adjusted. Releasing the spring-loaded release lever locks the assembly into the current vertical position.

***mini*Cart:** Bracing your palm against the rubber handrest, pull *upwards* on the release lever, located on the right side of the *mini*Cart, to release the mechanism. Hold the lever in the up position, until the desired height is

achieved. Releasing the spring-loaded release lever locks the assembly into the current vertical position.

SuperCart

***mini*Cart**

Figure 2-23. **Height Adjustment Release Lever**

LCD Display position

The LCD Display is mounted to a swivel mechanism that allows for rotation and tilting, to enable the user to optimize visibility of the screen. The tilt angle may be adjusted by grasping the sides of the LCD Display and pivoting to the desired viewing angle. The LCD Display should be tilted fully forward to a horizontal position when the SuperCart is being transported.

NOTE: The LCD Display contains an internal tilt-angle sensor switch that is used to blank the screen (go into a sleep mode) when the LCD Display is folded forward past an angle of approximately 60 degrees. This automatic blanking (and unblanking) of the LCD Display, while tilting it fore-aft, is normal on the **z.one** SuperCart.

Figure 2-24. **LCD Display Positioning (SuperCart)**

In addition, the LCD Display may be rotated on its swivel base to allow better viewing when the user is positioned on either side of the SuperCart while performing a patient examination.

***mini*Cart:**

On the *mini*Cart, for exclusively using centralized (centered) viewing, or for locking the LCD Display from rotating during transport, a spring loaded center-locking pin is provided. The knob for positioning the locating pin, is located below the display pedestal. For unrestricted rotation, the center-locating pin can be positioned into a constant **Off** (retracted) position, by pulling fully down on the knob and rotating it approximately 90 degrees.

Repeating the rotation of the knob to one of the two 180 degree release positions, will restore the center-locking operation.

Figure 2-25. **LCD Display Rotation & Locking (*mini*Cart)**

*mini*Cart Enhanced Keyboard Access

To provide full functionality, when the Scan Engine is docked, the *mini*Cart includes an Enhanced Keyboard. The Enhanced Keyboard is mounted to a retractable shelf that allows for stowage during system transport. To access the Enhanced Keyboard, grasp either edge of the retractable shelf, and slide it towards you.

Figure 2-26. ***mini*Cart Enhanced Keyboard Access**

SuperCart Rear I/O Panel

On the rear of the SuperCart, there is an input/output (I/O) panel for connecting peripheral devices.

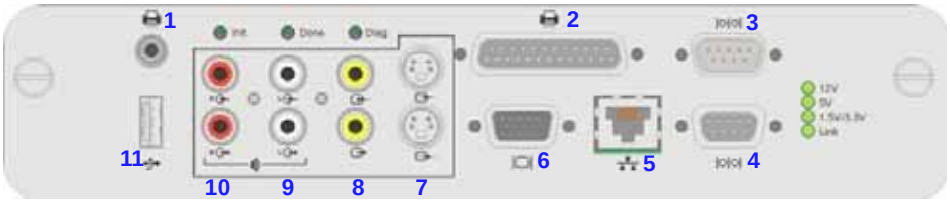


Figure 2-27. **SuperCart Rear I/O Panel**

Table 2-1 explains the connector functions.

Table 2-1. **Connector Functions**

Jack #	Function	Direction
1	Remote Print “Expose” (External Printer Trigger)	Output
2	*Parallel Printer (currently not supported)*	Output
3	RS-232 Serial Port A (Export Calc Data)	Input/Output
4	RS-232 Serial Port B (Export Calc Data)	Input/Output
5	Ethernet 10/100BaseT - (Network)	Input/Output
6	SVGA Video - (External Monitor)	Output
7	S-Video, NTSC/PAL - (OUT = bottom, IN = top)	Input/Output
8	Composite Video, NTSC/PAL - (OUT = bottom, IN = top)	Input/Output
9	Audio, LEFT - (OUT = bottom, IN = top)	Input/Output
10	Audio, RIGHT - (OUT = bottom, IN = top)	Input/Output
11	USB (2.0) Port (to be supported 2.0> Software)	Input/Output

*mini*Cart Rear I/O Panel

The *mini*Cart includes an integrated USB 2.0 compliant hub. Two of the hub's ports are brought out to external connections for operator use.

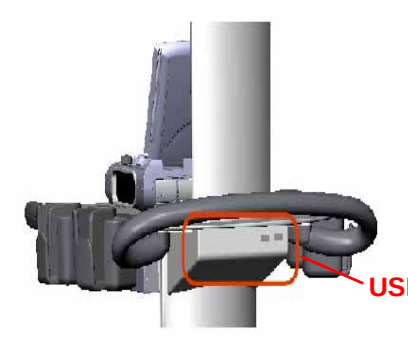


Figure 2-28. ***mini*Cart Rear I/O Panel (USB Hub)**

User Controls

The “User Control” on the **z.one** includes keys, menu items, Menu Control, and a trackball. Detailed information on the control, relevant to each system operating modality, are discussed in the respective chapter and section.

SuperCart User Interface Functions

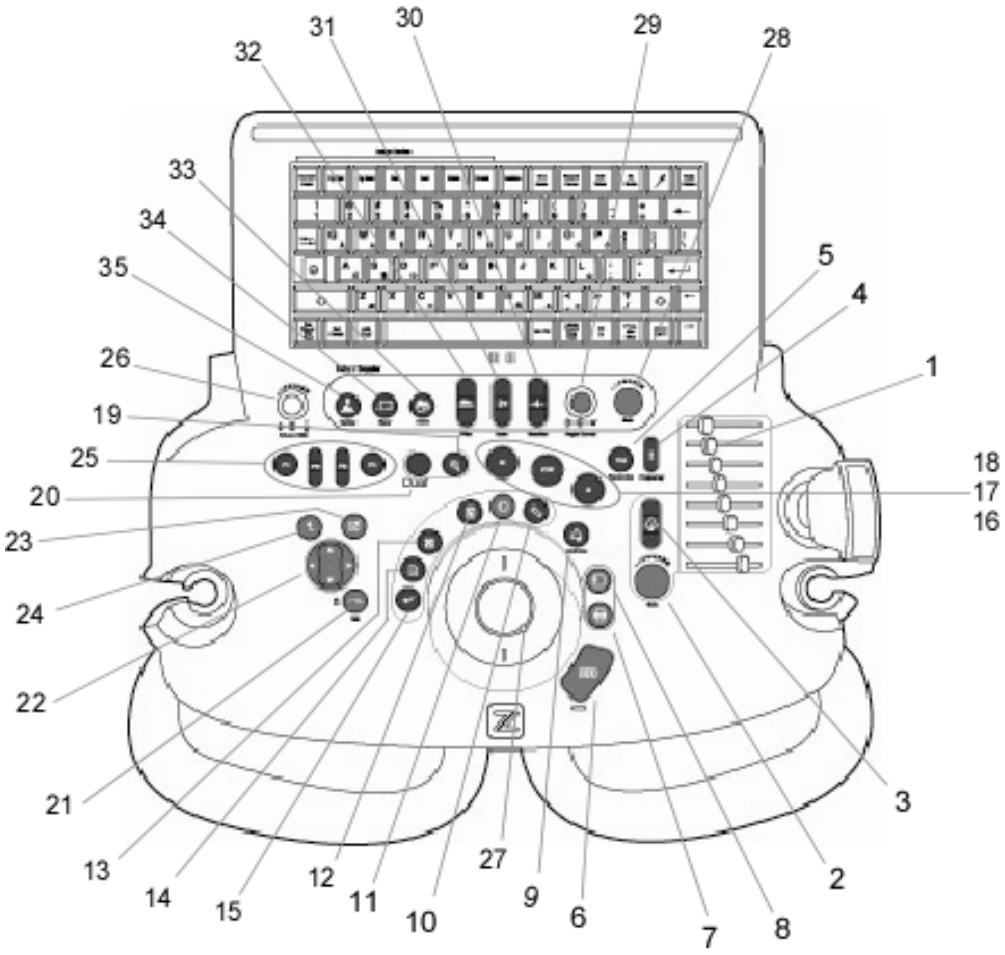


Figure 2-29. **SuperCart User Interface Layout**

Number	System Control	Description
1	TGC Slidepots	Changes gain of image at discrete depth.
2	GAIN	Changes master gain of Tissue image in B-Mode and M-Mode.
3	DEPTH	Rocker switch enables increasing / decreasing imaging depth of the display.
4	FREQUENCY	Rocker switch enables increasing / decreasing transmit frequency.
5	HARMONICS	Toggles the activation / deactivation of tissue harmonics imaging mode.
6	FREEZE	Halts or restarts active imaging on the display.
7	PRINT	Sends current image to device(s) previously specified in System Setup menu (internal compactflash, DICOM printer, DICOM store). When external printer is selected, key press initiates external print trigger signal to B / W printer. NOTE: The PRINT key may also be configured to initiate the same storage operations as the STORE key.
8	STORE	Stores current still image, or clip store sequence, to device(s) previously specified in System Setup menu (internal compactflash, DICOM printer, DICOM store). When external printer is selected, key press also initiates external “print trigger” signal to the external printer.
9	OPTIMIZE	Enables **Auto DGC** and **Sound Speed Correction**
10	MEASURE	Brings up dynamic caliper (live) or calculation menu (frozen).
11	**SET**	Used to toggle the function of active items on display.
12	CALC	Brings up Calculation tools on the display.
13	DELETE (Calc)	Deletes active Calculation tool from the display.

Number	System Control	Description
14	REPORT (Calc)	Displays the Calculation Worksheet / Report for the active Exam Type.
15	ENTER (Calc) / DUAL:Toggle	Shared function key: **Calc Ops**: Key ends the current Calc process, and produces a result. **DUAL Mode**: Toggles between two side-by-side displayed images, in selecting which will be "Active" / "Selected"
16	C	Color (Doppler) Mode, activates / deactivates.
17	PW	Pulsed Wave (Doppler), activates / deactivates.
18	M	M-mode (tissue motion), activates / deactivates.
19	ZOOM	Initiates the variable image magnification process.
20	DUAL	Activates the DUAL imaging (side-by-side) mode
21	TAB	Advances through four on-screen menus (Imaging, Presets, Patient Info, Tools).
22	Menu Control	Functions like a computer mouse or joystick, for scrolling through the on-screen menu selections Up / Down arrows scroll to selections Left / Right arrows toggle through values
23	SELECT	Activates currently highlighted selection in the on-screen menu.
24	BACK	Returns back one window, in the on-screen display menu.
25	F1-F4	Function keys, user configurable in System Setup menu.
26	VOLUME-MIC	Push-button (in center) turns on / off microphone activation. Rotary knob (outer ring) changes the on-board speaker volume.
27	Trackball	Used for positioning the cursor, defining size / position of ROE in color mode, positioning measurement tools, reviewing clip store images, and navigating form / tables / worksheets / reports.
COLOR/DOPPLER CONTROLS		
28	GAIN	Changes master gain for Color and PW Doppler modes.

Number	System Control	Description
29	ANGLE CORRECT	Push-button activates / toggles Doppler angle correction tools. Rotary knob makes fine adjustments to angle correction.
30	BASELINE	Changes Doppler Velocity (PW and Color) zero reference baseline.
31	SCALE	Changes Doppler Velocity (PW and Color) range.
32	FILTER	Changes high-pass filter, used in Color and PW.
33	INVERT	Switches the blood flow mapping direction, in Color and PW.
34	STEER	Toggles through 3 (center, left, right) steered Doppler options for Linear transducer(s).
35	UPDATE SIMULTANEOUS (DUAL):	Shared function key: Toggles Doppler update modes, or toggles ***Simultaneous*** sub-set operation in DUAL mode **PW Doppler**: Toggles between three possible update modes. 1) Simultaneous live updating of the PW and 2D imaging mode(s) (B-mode in duplex, and B-mode and Color in triplex) 2) Live updating of PW strip with a frozen 2D reference image 3) Live updating of 2D mode image with a frozen PW strip **DUAL Mode**: Toggles On / Off ***Simultaneous*** (side-by-side) update

SuperCart Keyboard Functions

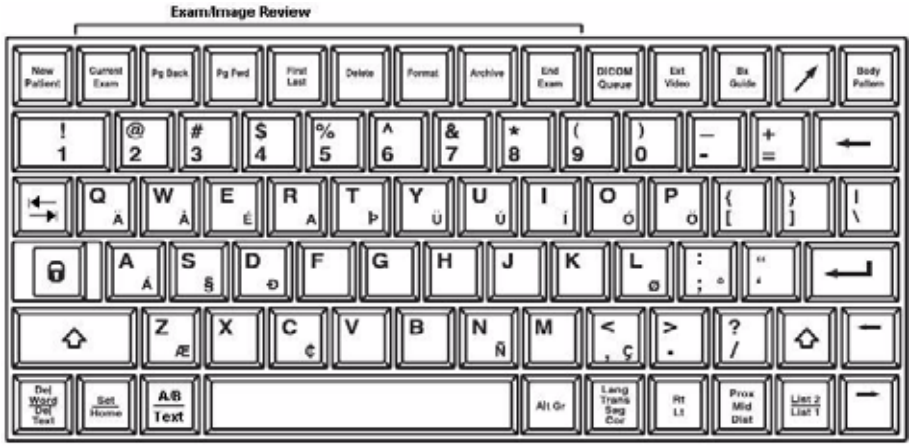


Figure 2-30. **SuperCart Keyboard Layout**

Table 2-2. **SuperCart Keyboard Functions**

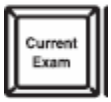
Key	System Control	Description
	NEW PATIENT	This is a toggle key. The first press displays the Patient Information page. The second press returns to the imaging display.
	CURRENT EXAM	If there is an exam in progress, pressing this key displays the in-progress exam's images, with the most recently stored image displayed first. If there is no exam in progress, pressing this key has no effect.
	PG BACK	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key displays the previous image or a page of images if in a multi-image display format. If there are no further images, the key press has no effect.
	PG FWD	Same as PG BK, except the image advances in direction.
	FIRST LAST	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key toggles the display between the first stored image (or first page of images in a multi-image display format) and the last stored image (or last page of images in a multi-image display format).

Table 2-2. **SuperCart Keyboard Functions**

Key	System Control	Description
	DELETE	This key only works when in an in-progress exam review or in an archived exam review. When an image has been selected, pressing the Delete key tags the image for deletion by drawing a red **X** through it. If the selected image already has been tagged for deletion (red **X**), pressing the Delete key removes the red **X**, untagging the image.
	FORMAT	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key toggles the display between the following image formats: ■ 2 x 2 [displaying 2 rows of 2 images (4 images)] ■ 3 x 2 [displaying 2 rows of 3 images (6 images)] ■ A full-size image
	ARCHIVE	This is a toggle key. The first press displays the Patient Selection Table. The second press returns to imaging.
	END EXAM	When an exam is in progress, pressing the End Exam key closes the exam. If no exam is in progress, pressing this key has no effect.
	DICOM QUEUE	This is a toggle key. The first press displays the DICOM queue. The second press returns to imaging.
	EXT VIDEO	External Video. This is a toggle key. There are three options: ■ The first press selects external S-Video (from the rear I/O panel) to display on the SuperCart's monitor. ■ The second press selects external composite video in (from the rear I/O panel) to display on the SuperCart's monitor. ■ The third press returns to using internal **z.one** system video (VGA) to display on the SuperCart's monitor.
	BX GUIDE	Biopsy guide. This is a toggle key. There are two options: ■ The first press displays the biopsy needle path guide. ■ The second press removes the biopsy needle path guide.

Table 2-2. **SuperCart Keyboard Functions**

Key	System Control	Description
	(Arrow)	This is a toggle key. It works when the image is live or frozen. Pressing the key displays an arrow graphic in the middle of the display. Up to 15 arrows may be displayed simultaneously.
	BODY PATTERN	This is a toggling key. Pressing the B**ody Pattern** key displays a Body Pattern for the Exam Type in use. Pressing the key again removes the displayed Body Pattern When a Body Pattern is displayed, pressing left / right on the Omni will cycle through all available Body Patterns.
	DEL WORD | DEL TEXT	Pressing **Del Text** removes all text annotations and arrow graphics displayed. Pressing Shift + **Del Word** deletes the most recently entered text annotation, whether it is free text, POT, or List entry.
	SET | HOME	Pressing **Home** moves the text annotation cursor to its default home position. Pressing **Shift + Set** Home will set the current cursor position as the new Home position.
	A / B | TEXT	Pressing Text will display the text annotation cursor. Pressing Text again will remove the text annotation cursor. **Shift + A/B** Text is not implemented.
	ALT GR	Used in conjunction with the QWERTY keyboard to support international characters.
	LONG TRANS SAG COR	This is a cycling key. Pressing this key will cycle between displaying LONG, TRANS, SAG, and COR.
	RT LT	This is a cycling key. Pressing this key will cycle between displaying RIGHT and LEFT.
	PROX MID DIST	This is a cycling key. Pressing this key will cycle between displaying PROX, MID, and DIST.
	LIST 2 | LIST 1	This is a cycling key. Pressing List1 will cycle between displaying items entered in List1. Pressing Shift+List2 will cycle between displaying the items entered in List2.

*mini*Cart Enhanced Keyboard Functions

Figure 2-31. ***mini*Cart Enhanced Keyboard Layout**

Table 2-3. **miniCart Enhanced Keyboard Functions**

Key	System Control	Description
	NEW PATIENT	This is a toggle key. The first press displays the Patient Information page. The second press returns to the imaging display.
	CURRENT EXAM	If there is an exam in progress, pressing this key displays the in-progress exam's images, with the most recently stored image displayed first. If there is no exam in progress, pressing this key has no effect.
	PG BACK	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key displays the previous image or a page of images if in a multi-image display format. If there are no further images, the key press has no effect.
	PG FWD	Same as PG BACK, except the image advances in forward direction
	FIRST LAST	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key toggles the display between the first stored image (or first page of images in a multi-image display format) and the last stored image (or last page of images in a multi-image display format).

Table 2-3. **miniCart Enhanced Keyboard Functions**

Key	System Control	Description
	DELETE	This key only works when in an in-progress exam review or in an archived exam review. When an image has been selected, pressing the Delete key tags the image for deletion by drawing a red **X** through it. If the selected image already has been tagged for deletion (red **X**), pressing the Delete key removes the red **X**, untagging the image.
	FORMAT	This key only works when in an in-progress exam review or in an archived exam review. Pressing this key toggles the display between the following image formats: ■ 2 x 2 [displaying 2 rows of 2 images (4 images)] ■ 3 x 2 [displaying 2 rows of 3 images (6 images)] ■ A full-size image
	ARCHIVE	This is a toggle key. The first press displays the Patient Selection Table. The second press returns to imaging.
	END EXAM	When an exam is in progress, pressing the End Exam key closes the exam. If no exam is in progress, pressing this key has no effect.
	DICOM QUEUE	This is a toggle key. The first press displays the DICOM queue. The second press returns to imaging.
	EXT VIDEO	External Video. This is a toggle key. There are three options: ■ The first press selects external S-Video (from the rear I/O panel) to display on the SuperCart's monitor. ■ The second press selects external composite video in (from the rear I/O panel) to display on the SuperCart's monitor. ■ The third press returns to using internal **z.one** system video (VGA) to display on the SuperCart's monitor.

Table 2-3. **miniCart Enhanced Keyboard Functions**

Key	System Control	Description
	BX GUIDE	Biopsy guide. This is a toggle key. There are two options: ■ The first press displays the biopsy needle path guide. ■ The second (and subsequent) presses will cycle through the display of the available needle path guide displays, removes the biopsy needle path guide after all paths have been displayed.
	(Arrow)	This is a toggle key. It works when the image is live frozen. Pressing the key displays an arrow graphic in the middle of the display. Up to 15 arrows may be displayed simultaneously.
	BODY PATTERN	This is a toggling key. Pressing the Body Pattern key displays a Body Pattern for the Exam Type in use. Pressing the key again removes the displayed Body Pattern. When a Body Pattern is displayed, pressing left / right on the Omni will cycle through all available Body Patterns.
	DEL WORD	Pressing **Del Word** deletes the most recently entered text annotation, whether it be free text, POT, or List entry.
	DEL TEXT	Pressing **Del Text** removes all text annotations and arrow graphics displayed, and resets the cursor to the current Home position.
	SET | HOME	Pressing **Home** move the text annotation cursor to its default home position. Pressing **Shift + Set** Home will set the current cursor position as the new Home position.
	A / B | TEXT	Pressing Text will display the text annotation cursor. Pressing Text again will remove the text annotation cursor. **Shift + A/B** Text is not implemented.
	ALT GR	Used in conjunction with the QWERTY keyboard to support international characters.
	LONG TRANS SAG COR	This is a cycling key. Pressing this key will cycle between displaying LONG, TRANS, SAG, and COR.
	RT LT	This is a cycling key. Pressing this key will cycle between displaying RIGHT and LEFT.

Table 2-3. **miniCart Enhanced Keyboard Functions**

Key	System Control	Description
	PROX MID DIST	This is a cycling key. Pressing this key will cycle between displaying PROX, MID, and DIST.
	LIST 1	Pressing List1 will display items entered in List1.
	LIST 2	Pressing List1 will display items entered in List 2.

Scan Engine User Interface Functions

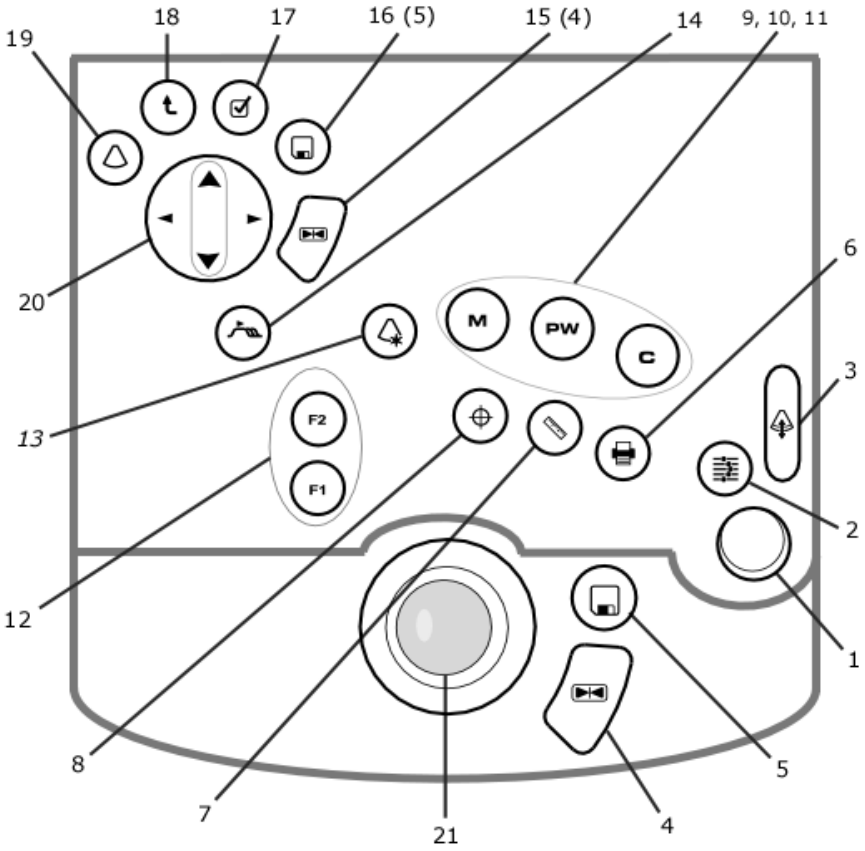


Figure 2-32. **Scan Engine User Interface Layout**

Number	System Control	Description
1	GAIN	There are two options: ■ Controls the overall gain for the active mode: B, M, Color, PW ■ Adjusts the TGC for the selected region when the virtual TGC graphic is displayed
2	TGC	Turns on the virtual TGC graphic
3	DEPTH	There are two options: ■ Adjusts the imaging depth shown on the display ■ Changes the selected TGC region when the virtual TGC graphic is displayed
4, 16	FREEZE	Halts or restarts active imaging
5, 17	STORE	Stores current still image, or clip store sequence, to device(s) previously specified in System Setup menu (internal compact flash, DICOM printer, DICOM store). When external printer is selected, key press also initiates external "print trigger" signal to the external printer
6	PRINT	Prints the current images (s) to selected printer, by initiating an external “print trigger” signal. NOTE: The PRINT key may also be configured to initiate the same storage operations as the STORE key.
7	MEASURE	Brings up dynamic caliper (live) or generic measurement menu (frozen)
8	**SET**	Used to toggle the currently selected item / function on-screen
9	C	Color (Doppler) mode, activates / deactivates
10	PW	Pulsed Wave (Doppler), activates / deactivates
11	M	M-Mode (tissue motion), activates / deactivates

Number	System Control	Description
12	F1, F2	Function keys, user configurable in System Setup menu
13	OPTIMIZE	Enables **Auto DGC** and **Sound Speed Correction**
14	TAB	Advances through the four (4) on-screen main menus (Imaging, Presets, Patient Info, Tools)
15, 16	see item 4 and 5 above	
17	SELECT	Activates the currently highlighted selection in the on-screen menu
18	BACK	Returns back one window, in the on-screen display menu
19	MODE	**Scan Engine Standalone**: Brings up the active scanning mode (C, PW, M) selection screen **Scan Engine docked in *mini*Cart**: Toggles ON / OFF the **Mirror Image** function
20	Menu Control	Functions like a computer mouse or joystick, for scrolling through the on-screen menu selections Up / Down arrows scroll to selections Left / Right arrows toggle through values
21	Trackball	Used for positioning the cursor, defining size / position of ROI in color mode, positioning measurement tools, reviewing clip store images and navigating form / tables / worksheets / reports

Menus

Figure 2-33. **Imaging Tab Menu with Selections**

Menus for the **z.one** are accessed in the Control area of the LCD Display on both the SuperCart and the Scan Engine. On the Scan Engine, virtually all controls can be accessed from the menus. The SuperCart has more limited menu selections because more of the functions may be accessed directly via dedicated keys on the Control Panel.

NOTE: When the z.one is being operated as a SuperCart (Scan Engine in the docked mode) the pop-up control menu is automatically hidden during periods of non-use. If the pop-up menu is currently not displayed (due to inactivity) pressing any of the menu control keys on the SuperCart will to "wake up" (display) the menu.

*All users must be familiar with the following procedure, which is abbreviated to "***Select***" in the operational instructions in subsequent chapters.*

To select a control from a menu

1. To view the desired menu, do the following:
   - To activate the menus, press any of the menu controls.
   - Instructions for calling up other menus are given in the context of the related operational instructions.
2. To highlight the desired control (menu item), position the highlight using the Up and Down arrows on the Menu Control.
   - The resulting behavior of the system is determined by the control selected.

- For menu selections that have variability, once the desired control function is highlighted, the “LEFT” and “RIGHT” arrow functions of the Menu Control are used to change the value/setting.
- For On/Off only selections, once the desired control function is highlighted, the “**Select**” key is used for toggling the state of that control.
- In some cases, selecting the control allows the user to view another menu. All menus are navigated in the same way.

3. To return to the menu, press **Back**.

Tabs

The four tabs are the top-level menus for the imaging modes, exam presets, patient information, and system tools. Repeatedly pressing the **Tab** key will sequence through the four available top level menu tabs.

Imaging tab

The Imaging tab menu lists the controls available in the active imaging mode. B-mode imaging is the system default, so the Imaging tab displays the B-Mode menu by default.

Presets tab

A Preset is a complete set of imaging parameters optimized for a specific exam type.

The Presets tab menu is a quick and convenient way to switch from one to another of the Presets defined for the exam type.

Figure 2-34. **Presets Menu Tab with Selections**

Patient tab

Use the Patient tab to view the Patient Information form. Refer to "Patient Information Form" on page 3-1. The Patient tab allows access to patient demographic information. Select Exam Type and Preset when beginning a new study.

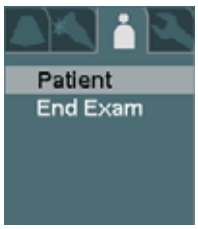


Figure 2-35. **Patients Menu Tab with Selections**

Tools tab

On the Scan Engine, the Tools tab includes access to the following functions:

- **Queue Admin** (DICOM)
- **Annotate**
- **Body Patterns**
- **View Current**

- **View Archive**
- **Preset Admin**
- **System Setup**

The **System Setup** menu offers the following selections:

- **Display**
  - Idle mode settings
  - Audio / video settings
  - Institution name / address
  - Time / Date
  - Bar Pattern - onscreen display test pattern
- **Imaging**
  - Exam category (default)
- **Touchscreen** (calibration)
- **Function keys** (assignment of “F1-F4” keys)
- **Calcs** (configuration)
- **Annotations** (configuration)
- **Archive**
  - Media (removable media configuration)
  - Print / Store (key function assignment, configuration)
- **DICOM** (configuration menus)
- **Network** (TCP / IP network configuration)
- **Security** (log-on configuration)
- **Serial Port** (OB report table output to external devices)
- **Diagnostics (**User Diagnostic Panel)

Menu icons

Menu items display with icons to the left, which are used to select an action associated with the control.

Table 2-4.

Icon	Control	Selection and Action
	There is no icon for this function	Press **Select** key to view the submenu associated with this control.
	Toggle	Press **Select** key to toggle between On and Off states. The icon is green in the On state.
	Factory Preset (toggle)	This control is used in the Preset tab only. Press **Select** to toggle between On and Off states.
	Incrementable / Decrementable function	Toggling the “LEFT” (<) or “RIGHT” (>) arrows, on the **Menu Control**, allow for incrementing / decrementing the associated (highlighted) operating control function.
	Cine Control Horizontal Slider	This control used for sequencing through the frames reviewed in a clip store imaging sequence

3

Imaging

Preparation for Imaging

Patient Information Form

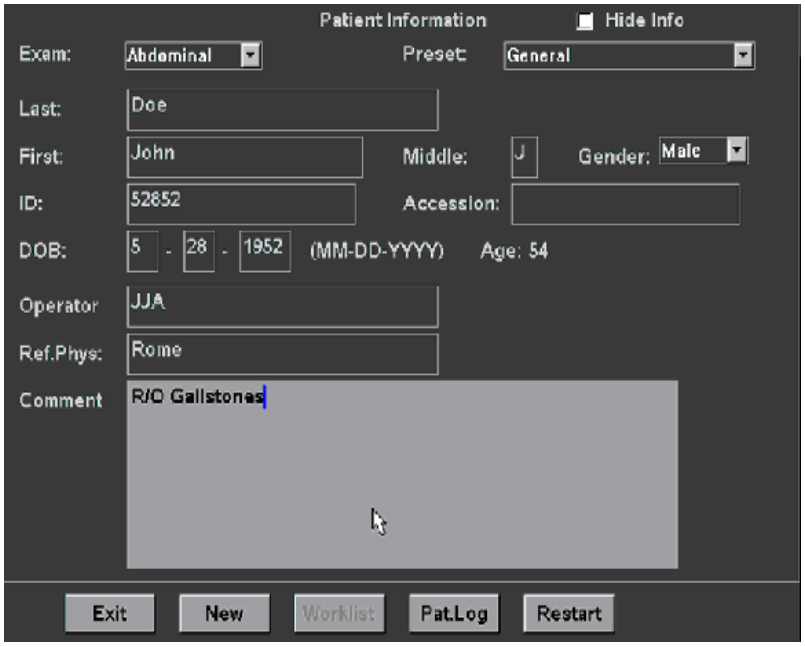


Figure 3-1. **Patient Information Form with Exam Type Selection List**

Selecting Patient from the Patient tab displays the Patient Information form.

Exam record data

The Patient Information form is essentially the record of the exam (patient ID and demographic data, date and time of the exam, salient clinical details). Data from the Patient Information form is used to name the exam directory in the internal CompactFlash archive.

Complete the Patient Information form before beginning imaging of the patient, to ensure that the correct Exam Type and Preset are activated, and that the patient's images and study data are stored in the correct exam directory. When images are stored, the DICOM stores the image and data files with the correct patient's medical records on the network archive.

If DICOM has been activated on the system, many data fields in the Patient Information form are completed automatically, when the user selects the patient from the DICOM Worklists.

Hide Info

Selecting the optional "***Hide Info***" box, at the top of the Patient Information form, will result in hiding all patient ID information from the active image display screen, and on all subsequent stored images sent to archive.

Open an exam

Storing the first image opens a new exam.

Create the exam directory

Storing the first image creates the exam directory on the internal CompactFlash storage.

Select the Exam Type and Preset

Select the Exam Type and Preset from selection lists on the Patient Information form. Some data fields are Exam Type specific, so the configuration of the new Patient Information form may change after the Exam Type has been selected.

For those Exam Types and Presets for which there is a calculations package, selecting the Exam Type and Preset for the exam activates the measurements and calculations package.

Close an exam

Selecting New from the Patient Information form and answering “Yes” to the displayed message closes an exam. Pressing the **End Exam** key or power cycling the system (normal power off operation) also closes an exam.

Restart a closed exam

A previously closed exam can be restarted within the same calendar day of when it was opened. An exam can be restarted from the **Restart** soft key of the Patient Information form. New images and other data can be saved to the exam directory. The Patient Information form can be edited.

After a calendar day has ended, the exam directory is automatically archived. Image and data files in the directory are available from the archive, but no new images or data can be saved (added) to the exam directory.

Soft keys

Soft keys, to the left of the Patient Information form, have the following functions. Point with the trackball, and then press **Set** to activate the control.

New

Erases any previous data if the user confirms the message and closes any open exam.

Exit

Saves and closes the Patient Information form. For a new exam, create the exam directory. Activate imaging.

Restart Exam

Recalls a list of exams that meet the restart criteria.

Worklist

Displays the active Worklist if DICOM was configured and activated. Populates the Patient Information form with data entered in the Worklist.

Patient Log

Displays a list of all patients whose images are stored on the internal CompactFlash storage. Populates the Patient Information form with demographics data.

DICOM Worklist

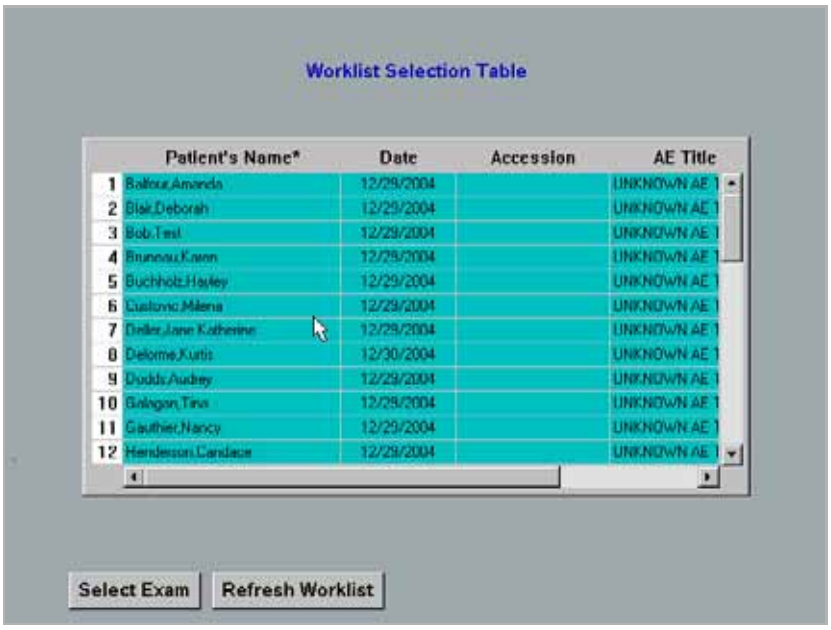

Worklist Selection Table
Patient's Name*
Date
Accession
AE Title
1 Balfour,Amanda 12/29/2004 UNKNOWN AE 1
2 Blair,Deborah 12/29/2004 UNKNOWN AE 1
3 Bob,Test 12/29/2004 UNKNOWN AE 1
4 Brunoau,Karen 12/29/2004 UNKNOWN AE 1
5 Buchholz,Hayley 12/29/2004 UNKNOWN AE 1
6 Custovic,Milena 12/29/2004 UNKNOWN AE 1
7 Diller,Jane Katherine 12/29/2004 UNKNOWN AE 1
8 Delorme,Kurtis 12/30/2004 UNKNOWN AE 1
9 Dodds,Audrey 12/29/2004 UNKNOWN AE 1
10 Gringon,Tina 12/29/2004 UNKNOWN AE 1
11 Gauthier,Nancy 12/29/2004 UNKNOWN AE 1
12 Henderson,Candace 12/29/2004 UNKNOWN AE 1
Select Exam
Refresh Worklist

Figure 3-2. **DICOM Worklist**

Activation of the DICOM modules enables exam scheduling data to be transmitted to, and displayed on, the **z.one**. The user can view an interactive Worklist, i.e., a schedule of exams and patient data. A Worklist application available on the network is configured on the **z.one** to match the requirements of the department.

When a new exam is initiated from the Worklist, some data fields on the Patient Information form are automatically completed from data in the Worklist entry.

Beginning a New Exam

To begin a new exam

1. To view a new Patient Information form, activate the Patient tab.

   SuperCart & *mini*Cart: Press the **New Patient** key on the upper left of the keyboard.

   Scan Engine: Tab to the **Patient** tab, and then select **New**.

2. To select the Exam Type and Preset, do the following:

   a. Using the trackball, point to the down arrow of the Exam data field. Press **Select** to drop down the selection list. Select the correct Exam Type.

b. After selecting the Exam Type, the Presets menu automatically drops down with the cursor on the first Preset of the menu. The Patient Information form configuration may change, depending on the Exam Type selected.

NOTE: The Presets menu will not appear unless a transducer is attached to the system. Presets are transducer-specific. Make sure that the correct transducer is attached for the application

3. To enter the patient demographic and clinical data, do the following:

   SuperCart & *mini*Cart: Use the keyboard to enter text. Press **Tab** on the keyboard to advance to the next data field.

   Scan Engine: View the VKB (*Virtual Key Board*). Using the stylus, touch keys to enter text. Press **Tab** on the VKB to advance to the next data field.

4. If it is desired to not show patient information data on the actively displayed images, select the **Hide Info** box at the top of the menu.

5. To save and exit, do the following:
   When the form is complete, select **Exit** to save the Patient Information form and return to the image display. Verify that the patient's name and the correct Exam Type and Preset display at the top of the Image area.

NOTE: NOTE: You can also Exit by pressing the Freeze key

To begin a new exam from a DICOM Worklist

1. To view a new Patient Information form, activate the Patient tab.

2. To view the Worklist, press the **Worklist** soft key. The open Worklist displays.

3. To select the desired exam, do the following:

   Using the trackball, point to the Worklist entry for the desired exam. Press **Set** once to highlight the exam. Press **Set** again to select or highlight the exam, then move the cursor over the **Select Exam** softkey and press **Set**.

   A Patient Information form displays. Patient demographic and some other data fields are automatically completed from information in the Worklist entry.

4. To complete the Patient Information form, do the following:

   Complete the remaining data fields, and make any necessary changes to them.

   SuperCart & *mini*Cart: Use the keyboard to enter text. Press **Tab** on the keyboard to advance to the next data field.

   Scan Engine: View the VKB. Using the stylus, touch keys to enter text. Press **Tab** on the VKB to advance to the next data field.

5. To save and exit, do the following:

   When the form is complete, select **Exit**, or press **Freeze**, to save the form and return to the image display. Verify that the patient's name and the correct Exam Type and Preset display at the top of the Image area.

To edit a Patient Information form

The Patient Information form can be edited only while the exam is open (i.e., within a calendar day of the beginning of the exam). In addition, you can re-start and edit The Patient Information form for any exam that was performed within the last calendar day.

1. Press the **New Patient** key. The LCD Display displays a list of exams on the internal CompactFlash storage.

2. To select Edit under the desired exam, do the following:

   SuperCart & *mini*Cart: Use the trackball to highlight the desired entry. Press **Set**.

   Scan Engine: Use the trackball to place the cursor over the desired entry. Press **Set**.

   Highlight cells to edit. Use the backspace key to edit, or tab through to each cell to be edited. Refer to "To Open an Archived Exam for Review (SuperCart or miniCart)" on page 6-11.

3. To edit data fields (as required), do the following:

   Use the trackball to position the cursor in the desired data field.

   SuperCart & *mini*Cart:
   – To delete text: Use **Backspace** on the keyboard to delete single characters. Highlight the entire data field and use **Backspace** to clear the entire data field.

   – To enter text: Use the **Tab** key on the keyboard.

   Scan Engine:
   – To delete text: Use **Backspace** on the VKB to delete single characters. Highlight the entire data field and use **Backspace** to clear the entire data field.

   – To enter text: Use the stylus on the VKB.

4. When the Patient Information form is complete, select **Exit**, or press **Freeze,** to save the form and return to the image display.

Presets

Presets are designed to optimize the ultrasound image for a particular application. Imaging Presets are exam-type specific. To ensure optimal

performance, always start by attaching the transducer that is appropriate for the application, selecting the appropriate exam type and then selecting the desired Preset.

NOTE: For information on ***Storing*** and ***Backing-Up*** of **Presets**, refer to "Backing-Up System/Presets" on page 10-6of this manual.

To select the desired Preset (from the Imaging screen)

To select a Preset (on the SuperCart, *mini*Cart or Scan Engine) go to the **Preset** tab and select the desired Preset.

To create a new User Preset

1. Attach the transducer that is appropriate for the application
2. Using the Tab key, tab to the **Presets** tab
3. Load the factory-installed Preset to be modified.

NOTE: Choose a Preset that is the closest to your desired Preset parameters

4. Tab to the **Imaging** tab and modify any of the values on the factory-installed Preset, by adjusting any desired system imaging parameters (user controls) to the values you wish to be stored to this new User Preset.

NOTE: Do this for each mode, i.e. B, C, PW, M

5. Tab to the Presets tab.
6. Select or highlight the **Preset Management** menu item.
7. Select **Create a Preset**.
8. Name the new Preset.
9. Highlight **Apply** in the menu, to save the new Preset.

NOTE: You can name the new Preset the same name as the Factory Preset. The Factory Presets will have a "Z" icon next to the label. The User Presets will have a "dot" icon next to the label. These icons distinguishes the Factory from the User Presets for easy identification.

To set a default Exam Type

1. Tab to the **Tools** tab.
2. Highlight and select **System Setup** menu item.
3. Highlight and select **Imaging** menu item
4. *Check* the box to the left of **Exam Category** (Type) that you wish to become the default **Exam Type** for the current transducer.
5. Highlight and select **Apply**, to activate the new setting

   This Exam Type is now the default for the current probe type.

To set a default Preset

1. Attach the transducer that is appropriate for the application
2. Tab to the Presets tab.
3. Load the desired imaging **Exam Type**.
4. Return to the Presets tab.
5. Select the desired **Preset**.
6. Select the **Preset Management** menu item.
7. Highlight and select **Set Default.**

   This Preset is now the default for the selected exam type.

To Enable/Disable a Factory or User Preset in Menu

NOTE: ***Factory*** Presets are identified by a Zonare "Z" inside the bubble to the left of their name in the main Presets menu. Customized ***User*** Presets can be identified by an empty bubble to the left of their name.

1. Tab to the Presets tab.
2. Ensure that the desired **Exam Type** is currently selected

NOTE: If not, go to the Presets tab, and select desired **Exam Type** prior to beginning the enable/disable steps below.

3. Select the **Preset Management** option.
4. Highlight and select **Enable/Disable** option.
5. *Uncheck* the box to the left of any *Factory* or *User* Preset that you wish to **REMOVE** (Disable) from the main Presets menu.
6. Highlight and select **Apply**, to activate the new settings

   This Preset is now the default for the selected exam type

To Backup User "PRESETS" to USB Memory Stick

1. Insert the separate USB Memory Stick, that has been allocated exclusively for use as the **User Preset/User System Backup** media, into the USB port at the rear of the Scan Engine.
2. To access the **Backup/Restore** functions screen, select **Tools | Preset Admin**
3. Highlight and select **Preset Admin**
4. Highlight and select **Backup Presets**

   The User Presets currently configured on the **z.one** will now begin copying to the USB Memory Stick, for backup storage.
5. At the conclusion of the backup transfer of **Preset** files, remove the USB Memory Stick from the Scan Engine, and store in a safe place for future use.

To Backup "SYSTEM" configuration to USB Memory Stick

1. Repeat steps 1-3, listed in the Presets backup above, for preparing the **User Preset/User System Backup** media and accessing the main backup/restore (**Preset Admin**) menu.
2. In the **Preset Admin** menu, highlight and select **Backup System**

   The customized **System** settings (DICOM parameters, Institution Name, Function Key operations, etc.) that are currently configured on the **z.one** will now begin copying to the USB Memory Stick, for backup storage.
3. At the conclusion of the backup transfer of **System** files, remove the USB Memory Stick from the Scan Engine, and store in a safe place for future use.

Function Keys

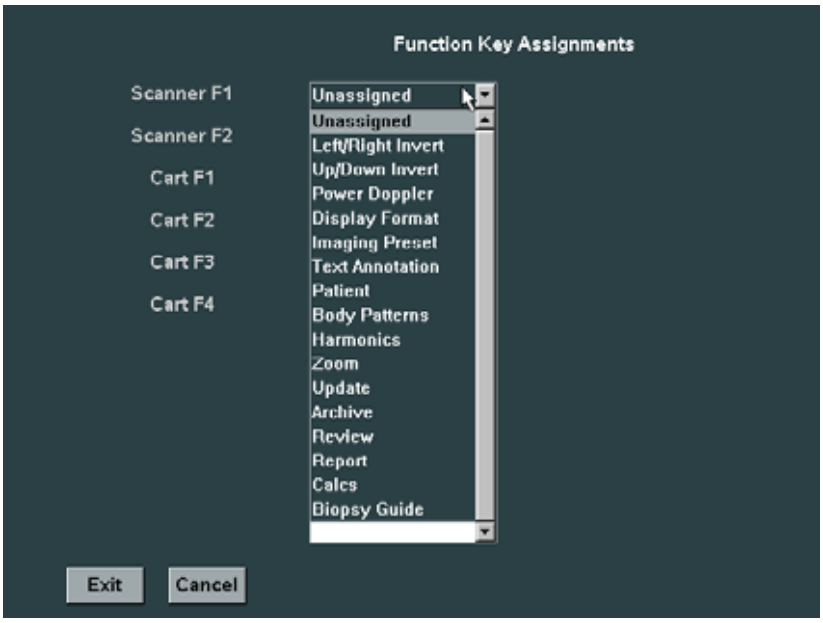


Figure 3-3. **Function Key Configuration Screen**

Function Keys are unassigned keys that can be programmed by the user. The Scan Engine has two programmable Function Keys; the SuperCart has four programmable keys.

To configure Function Key assignments

1. On the **Tools** tab, select **Sys Setup**

   Select **Function Keys** from the menu to view the Function Key Configuration screen. Refer to the "Function Key Configuration Screen" on page 3-10.

2. To change the Function Key assignment, do the following:

   Make a selection from the Function Key Configuration screen to assign that function to the key.

   There are two rocker keys available, which can be programmed to adjust a specified imaging parameter up or down.

   The Scan Engine and SuperCart function keys can be individually programmed to create custom function keys.

3. To verify the newly configured function key, press the function key to ensure that the desired operation begins.

Live and Frozen Images

Annotations, including text, arrows, and body pattern graphics can be used with both live and frozen images. Refer to Chapter 4, "Annotations."

Live images

All imaging parameters can be changed (see mode-specific tables in the following sections). However, except for simple depth measurements in B-mode, M-mode, and Color Doppler mode, and velocity measurements in PW mode, the generic measurement tools and application-specific calculation packages are not available. Refer to Chapter 5, "Measurements and Calculations".

Frozen images (clip review)

Use the trackball to move forward or backward in the clip. Since **z.one** stores preprocessed data in cine memory, clip review involves retrospective processing of the stored data. The major benefit of retrospective processing is that some imaging parameters (as marked by an ✱ in the mode-specific tables in the following sections) can be changed. The generic measurement tools and application-specific calculation packages can be used. Refer to Chapter 5, "Measurements and Calculations".

Brightness Mode (B-mode) Imaging

Figure 3-4. **B-mode Image Display Format**

The **z.one** is initialized for B-mode imaging at start-up. B-mode operation is the basis for all other imaging modes.

B-mode Menu - (SuperCart & Scan Engine)

SuperCart Scan Engine

Figure 3-5. **B-Mode Menu (Imaging Tab) - SuperCart & Scan Engine**

B-Mode Touchscreen Menu - (*mini*Cart)

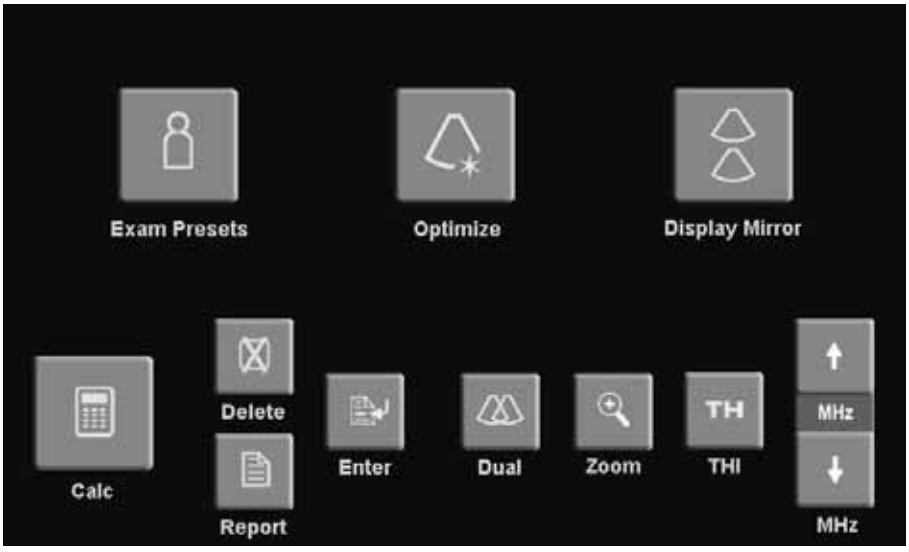


Figure 3-6. **B-Mode Touchscreen Menu - *mini*Cart**

Working with B-mode Imaging

1. For an optimal B-mode image, begin imaging with the settings implemented by the Preset. Then optimize the image if necessary. Refer to "Presets" on page 3-6.
2. To perform the required operations on the live image, refer to "Live and Frozen Images" on page 3-11 for operations that can be performed on a live image.
3. To freeze the image, press **Freeze**.
4. To perform retrospective processing on the frozen image, refer to "Live and Frozen Images" on page 3-11 for operations that can be performed on a frozen image.

"Display Mirror" Operation (*mini*Cart only)

In the *mini*Cart configuration of the **z.one** product, the 5" LCD Display on the Scan Engine normally displays the Touchscreen controls, and the 15" LCD Display on the miniCart displays the ultrasound images.

In special cases where it is desired to temporarily display the ultrasound imaging screen on the main *mini*Cart display, and the 5" LCD Display on the Scan Engine, a **Display Mirror** feature is provided.

Turning "ON" the **Display Mirror** function:

1. Press the **Display Mirror** softkey on the touchscreen.

OR

1. Press the **Mode** button on the Scan Engine.

Turning "OFF" (returning to the Touchscreen) the **Display Mirror** function:

1. Press the **Mode** button on the Scan Engine, a second time.

"DUAL" Imaging Mode - Introduction

Turning on the **DUAL** imaging function will cause the system to display two side-by-side images (referred to as image A and image B for the purpose of

this document). Only non-strip imaging modes (i.e. B-mode, Color Doppler, or Power Doppler) are supported for DUAL image mode

In basic DUAL mode one of the two images displayed on the screen will be active (live updating) while the other image is static (not updating).

In addition to basic **DUAL** mode, a subset ***Simultaneous*** DUAL mode may be selected. In the ***Simultaneous*** DUAL mode both images (A and B) displayed on the screen will be dynamically active (live updating). During ***Simultaneous*** DUAL mode, one image will be selected as the "active" image (indicated by the "**Z**" Zonare logo). User controls are applied in the following manner during ***Simultaneous*** DUAL mode operation:

- **Pre-Processing** functions (A Output, C, etc.) - "ACTIVE" image only
- **Post-Processing** functions (Gain, Persistence) - BOTH images affected

"DUAL" Imaging Mode - Activation

1. To activate **DUAL** mode, do the following:

   SuperCart:
   – Press the **DUAL** key.

   ***mini*Cart:**
   – Press the **DUAL** softkey on the touchscreen.

   Scan Engine:
   – Using the **Menu Contro**l, scroll down to backlight the **Dual: Off** selection.

   – Using the **Left/Right** function of the **Menu Control**, toggle to the initial DUAL image (**A**)

2. Optimize the orientation on the patient's anatomy, user settings, and image quality, for the initial image displayed (**A**).

3. To toggle (activate) to the other DUAL image (**B**), do the following:

   SuperCart:
   – Press the shared-use **ENTER (Calc) /** (*DUAL:Toggle*) key.

   ***mini*Cart**:
   – Press the **ENTER** softkey on the touchscreen.

   Scan Engine:
   – Using the **Menu Contro**l, ensure that the backlight is selecting the **Dual** function.

– Using the **Left/Right** function of the **Menu Control**, toggle through to the activate the (**B**) DUAL image

4. Optimize the orientation on the patient's anatomy, user settings, and image quality, for this second image displayed (**B**).

Simultaneous DUAL Operation

1. While already in DUAL mode, to activate ***Simultaneous*** DUAL mode, do the following:

SuperCart:
– Press the shared-use **UPDATE** / **(***Simul-Dual***)** key.

***mini*Cart:**
– Due to the touchscreen control environment on the *mini*Cart, the shared-use UPDATE (Simul-Dual) softkey does not exist when the system is operating in B-Mode only. In B-Mode only, in order to activate ***Simultaneous*** DUAL mode on the *mini*Cart, one of the user-defined function keys (**F1**) will need to be assigned to the **Update** function.

– IF the system is being operated in the *shared* operation mode (B-Mode / Color), press the shared-use B UPDATE / (*Simul-Dual*) softkey on the touchscreen

Scan Engine:
– Using the **Menu Contro**l, scroll down to backlight the **Simul:Dual** selection.

– Press the **Enter** key (or use the **Left/Right** function of the **Menu Control**) to toggle On / Off ***Simultaneous*** DUAL imaging mode.

Optimize Feature

NOTE: A transducer must be attached to the Scan Engine for this control to work. Optimize has two separate functions: 1) Overall/DGC gain adjustment; 2) Sound Speed Compensation. Both features can be activated simultaneously, or separately, depending on the configuration. Refer to the Optimize Configuration Page

1. To activate ***Overall/DGC Gain*** optimization, do the following:

SuperCart & **Scan Engine**:
– Press the Optimize key to automatically balance the Overall / DGC gain. The B-Mode image will adjust the brightness of the image to a Target Gain Offset value on top of the factory default brightness setting,

– The default Target Gain Offset value is user presetable via the configuration page: (Setup>Imaging).

– If the B-Mode overall gain is changed while Optimize = ON, the Target Gain value will be modified to reflect the new gain setting.

2. To activate ***Sound of Speed Correction***, do the following:

SuperCart & **Scan Engine**:
– Press the Optimize key to automatically compensate for the sound speed in tissue. The B-Mode image will pause momentarily, then adjust for the detected sound speed.

– The value for SSC is displayed as a Sound Speed Index (SSI) in the B-Mode data display, e.g. SSI=40

***mini*Cart**:
– Press the Optimize Touchscreen button or use the Optimize control button on the Scan Engine.

3. To exit the **Optimize** functions, do the following:

SuperCart & **Scan Engine**:
– A double click of the Optimize key will make Optimize = OFF

– The Overall Gain will remain at the current value

– The DGC values will reset and correspond to the DGC slider locations

– SSC will revert back to the preset Sound Speed Index Default (SSID) value

– The Target Gain will remain at the current value

***mini*Cart**:
– Press the Optimize Touchscreen button or use the Optimize control on the Scan Engine

B-mode Controls

✱ Indicates that this control is also available in retrospective processing.

To get to B-mode, refer to "B-mode Menu - (SuperCart & Scan Engine)" on page 3-12.

B Control	SuperCart & *mini*Cart	Scan Engine
Gain ✱ SuperCart Scan Engine	**SuperCart:** ■ Adjust Gain using the Tissue **Gain** knob. ***mini*Cart:** ■ Refer to Scan Engine controls	■ Adjust Gain using the **Gain** knob. ■ Highlight **Gain**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired receive gain. The selected value displays in the Image Information area.
Depth SuperCart Scan Engine	**SuperCart:** ■ On the **Depth** rocker key, press the **Up** to decrease depth; press the **Down** to increase depth. ***mini*Cart:** ■ Refer to Scan Engine controls.	■ On the **Depth** rocker key, press the **Up** to decrease depth; press the **Down** to increase depth. ■ Highlight **Depth**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired imaging depth. The selected value displays in the Image Information area.

B Control	SuperCart & *mini*Cart	Scan Engine
Harmonics SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the **TH** key to toggle On / Off tissue harmonic imaging. When harmonic imaging is active, an “H” displays in the Image Information area. ***mini*Cart:** ■ From the Touchscreen, press the **TH** key to toggle On / Off tissue harmonic imaging. When harmonic imaging is active, an "H" displays in the Image Information area.	■ Highlight **Harmonics**. Press **Select** to toggle between selecting / deselecting harmonic imaging mode. When harmonic imaging is active, an “H” displays in the Image Information area.
Frequency SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Frequency** rocker key, press the **Up** key to increase the transmit frequency; press the **Down** key to decrease the transmit frequency for the B-Mode image. The selected value is displayed in the Image Information area. ***mini*Cart:** ■ From the Touchscreen, on the **MHz** key, press the Up Arrow to increase the transmit frequency, press the Down Arrow to decrease the transmit frequency. The selected value is displayed in the Image Information area.	■ Highlight **Frequency**. Press **Left / Right** function on **Menu Control** to increase / decrease the desired transmit frequency for the B-Mode image. The selected value displays in the Image Information area.

B Control	SuperCart & *mini*Cart	Scan Engine
Zoom SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ ***Acoustic Zoom*** (During live scanning): Press **Zoom** key. The ROI (region of interest) box displays over the image. Define the ROI: Use the trackball. Press the Set key to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view. ■ ***Display Zoom*** (From a Frozen Image): Press **Zoom** key. The image magnifies 1.5X Press Depth rocker key up to increase magnification Press Depth rocker key down to decrease magnification Use Trackball to pan the image. Press Zoom to return to the normal view ***mini*Cart:** ■ ***Acoustic Zoom*** (During live scanning): From the Touchscreen Main Menu, Press Zoom key. The ROI (region of interest) box displays over the image. Define the ROI: Use the trackball. Press the Set key to toggle between ROI position and ROI size. Press Zoom to display the enlarged ROI. Press Zoom to return to the normal view. ■ ***Display Zoom*** (From a Frozen Image): From the Touchscreen Main Menu, press Zoom Key. The image magnifies 1.5X Press Depth rocker key up to increase magnification Press Depth rocker key down to decrease magnification Use Trackball to pan the image. Press Zoom to return to the normal view	■ ***Acoustic Zoom*** (During live scanning): Press **Zoom** key. The ROI (region of interest) box displays over the image. Define the ROI: Use the trackball. Press the Set key to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view. ■ ***Display Zoom*** (From a Frozen Image): Press **Zoom** key. The image magnifies 1.5X Press Depth rocker key up to increase magnification Press Depth rocker key down to decrease magnification Use Trackball to pan the image. Press Zoom to return to the normal view
Maps ✱ 	Highlight **Maps**. Press **Left / Right** function on **Menu Control** to select the desired tissue grey-scale map to be applied to the B-Mode image.	

B Control	SuperCart & *mini*Cart	Scan Engine
Dynamic Range *	■ Highlight **Dyn Range**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired dynamic range.increase	
L/R Invert *	■ Highlight **L/R Invert**. Press **Select** to invert the L / R orientation of the image. The probe orientation marker (Zonare "**Z**") moves from the left to the right of the Image area.	
U/D Invert *	■ Highlight **U/D Invert**. Press **Left / Right** function on **Menu Control** to invert the U / D orientation of the image. The probe orientation marker (Zonare "**Z**") moves from the top to the bottom of the Image area.	
Persistence *	■ Highlight **Persistence**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired level of frame averaging.	
Edge *	■ Highlight **Edge**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired image enhancement option.	
DGC * SuperCart Scan Engine	**SuperCart:** ■ Move a **DGC** slider to the right to increase gain, and to the left to decrease gain for the depth zone controlled by each slider. When TGC is being adjusted, the on-screen TGC graphic displays to the right of the image. ***mini*Cart:** ■ Refer to Scan Engine controls.	■ Press **DGC** key. The on-screen TGC graphic displays to the right of the image. The green highlight shows the active "slider." Turn **Gain** clockwise to increase gain and counter clockwise to decrease gain at the depth controlled by the active slider. Use the **Depth** rocker key to move up or down in selecting the active TGC slider for control by the Gain control knob. ■ Press **DGC** to save the settings and return to the menu.

B Control	SuperCart & *mini*Cart	Scan Engine
Optimize * SuperCart & Scan Engine miniCart	Overall / DGC Gain ■ Press the **Optimize** key (softkey on the *mini*Cart touchscreen) to automatically balance the Overall / DGC gain. The B-Mode image will adjust the brightness of the image to the default Target Gain value. Sound Speed Correction ■ Press the **Optimize** key (softkey on the *mini*Cart touchscreen) to automatically compensate for the sound speed in tissue. The B-Mode image will pause momentarily, then adjust for the detected sound speed. To exit OPTIMIZE mode ■ A double-click of the **Optimize** key will turn Optimize functions = OFF.	Overall / DGC Gain ■ Press the **Optimize** key to automatically balance the Overall / DGC gain. The B-Mode image will adjust the brightness of the image to the default Target Gain value Sound Speed Correction ■ Press the **Optimize** key to automatically compensate for the sound speed in tissue. The B-Mode image will pause momentarily, then adjust for the detected sound speed. To exit OPTIMIZE mode ■ A double-click of the **Optimize** key will turn Optimize functions = OFF.
A Output	■ Highlight **A Output**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired transmit power output level. The current transmit power level is displayed (as a percentage; 25%, 50%, etc.) in the Image Information area. The default value is 100%.	
Biopsy Guide SuperCart Scan Engine	**SuperCart:** ■ From the QWERTY keyboard, press **Bx Guide** key to toggle through the available guide lines, and biopsy guide on / off, in live or freeze modes. ***mini*Cart:** ■ Use either method. Both are available with the *mini*Cart.	Highlight **Bx Guide**. Press **Select** to toggle biopsy guide on / off.

B Control	SuperCart & *mini*Cart	Scan Engine
Dual: Off/On SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the key labeled **DUAL** to toggle the Dual imaging function On / Off. **NOTE:** The **Dual** imaging function allows for displaying two separate images on the screen (at the same time), for concurrent comparison / analysis. ***mini*Cart:** ■ Press the Touchscreen key labeled **DUAL** to toggle the Dual imaging function On / Off.	Highlight **Dual Off (On)**. Press **Left / Right** function on **Menu Control** to turn On / Off the dual image display function. **NOTE:** In addition to turning the Dual function On or Off, the **Left / Right** function on the **Menu Control** is used for sequencing through four (A, B, A:b, a:B) different **Dual** image display states.
Dual: Toggle SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the shared use Enter **(Calc)/Dual Toggle** key to change the selection of the“Active” / ”Selected” image (Left or Right image, as displayed on screen). ***mini*Cart:** ■ Press the Touchscreen key labeled **Enter** (Calc) / Dual Toggle softkey to change the selection of the"Active" / "Selected" image (Left or Right image, as displayed on screen)	Highlight **Dual Off (On)**. Pressing the **Left / Right** function on **Menu Control** will sequence through four (A, B, A:b, a:B) different **Dual** image display states. > A:b = Left image active / Right image static > a:B = Left image static / Right image active > A = Full sized Left image displayed > B = Full sized Right image displayed

B Control	SuperCart & *mini*Cart	Scan Engine
Simul: (Dual) SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the shared use **Update / Simul** key to toggle On / Off the **Simultaneous** Dual imaging update modality. **NOTE:** When **Simul Dual** is active, the two different images, potentially using different modalities (i.e. Color Doppler & Power Doppler) will be dynamically updated, simultaneously. When this function is *deselected* (standard Dual mode) one image will be static, while the other image is dynamically active. ***mini*Cart:** **NOTE:** The miniCart must be operated in shared B-Mode / Color mode, for the **Enter** (Calc) / Dual Toggle softkey to appear on the screen. The "F1" key can be assigned to the **Update** function, to achieve toggle of **Simultaneous** Dual, in B-Mode only. ■ IF in B-Mode / Color shared mode, press the Touchscreen **B Update** softkey (Update / Simul Dual Toggle) to toggle On / Off the **Simultaneous** Dual imaging update modality.	■ Highlight **Simul: Dual.** Press **Select** to toggle On / Off this function. **NOTE:** When **Simul Dual** is active, the two different images, potentially using different modalities (i.e. Color Doppler & Power Doppler) will be dynamically updated, simultaneously. When this function is *deselected* (standard Dual mode) one image will be static, while the other image is dynamically active.
MIC SuperCart - n / a - Scan Engine -	■ Press the **MIC** button (in the center of the VOL control knob) to toggle on / off the active recording mode for the built-in microphone on the UI of the SuperCart. An ICON, in the shape of a microphone, is displayed on the screen when the MIC is active.	■ n / a.

Motion Mode (M-Mode) Imaging

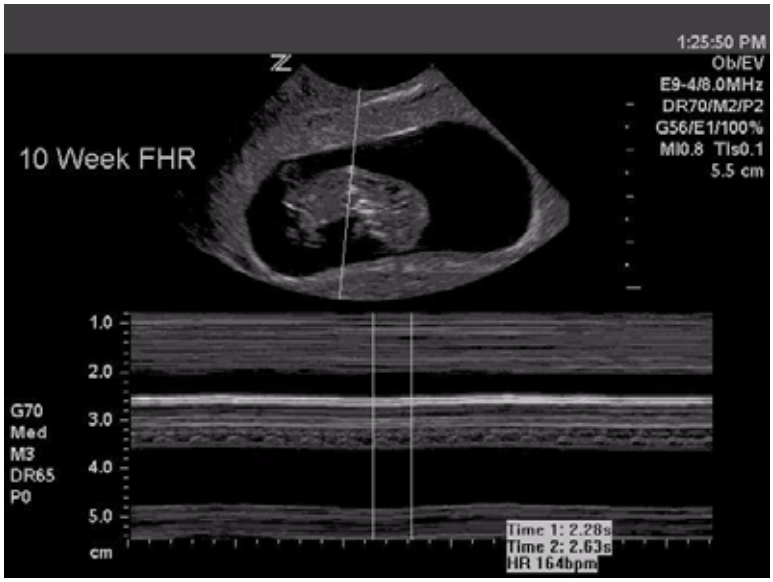


Figure 3-7. **M-Mode Image Display Format**

Motion mode (M-Mode) is used to quantify the dynamic movement of tissues. M-mode imaging begins with the acquisition of a B-mode image.

M-Mode Menu

SuperCart

Scan Engine

Figure 3-8. **M-Mode Menu (Imaging Tab) - SuperCart & Scan Engine**

Working with M-mode Imaging

1. Acquire the B-mode image. Refer to "B-mode Menu - (SuperCart & Scan Engine)" on page 3-12.
2. To initiate M-mode, do the following:

   Press **M**. Press **Menu control** to view the M-mode menu.

   An alternate method to initiate the Scan Engine is to press **Mode** to view the Mode menu. Select **M-mode**.

   The M-cursor bisects the B-mode image. The M-mode scroll begins.

   M-mode status information displays to the left of the M-mode strip.
3. To freeze the image, refer to "Live and Frozen Images" on page 3-11.
4. To perform retrospective processing (optional), use the retrospective processing controls (available for a frozen image), which are denoted by ∗ in the Controls table.
5. To return to B-mode (optional), press **M**.

M-mode Controls

✱ Indicates that this control is also available in retrospective processing.

M-Control	SuperCart & *mini*Cart	Scan Engine
Gain ✱ SuperCart Scan Engine	**SuperCart:** ■ Adjust Gain using the Tissue mode **Gain** knob. ***mini*Cart:** ■ Use the same method for the Scan Engine.	■ Adjust Gain using the **Gain** knob. ■ Highlight **Gain**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired receive gain. The selected value displays in the Image Information area.
Depth SuperCart Scan Engine	**SuperCart:** ■ On the **Depth** rocker key, press the **Up** key to decrease depth; press the **Down** key to increase depth. The selected depth is displayed in the Image Information area. ***mini*Cart:** ■ Use the same method for the Scan Engine.	■ On the **Depth** rocker key, press the **Up** key to decrease depth; press Down to increase depth. ■ Highlight **Depth**. Press **Left / Right** function on **Menu Control** to increase or decrease the B-Mode image to the desired depth. The selected depth is displayed in the Image Information area.

M-Control	SuperCart & *mini*Cart	Scan Engine
Zoom SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Zoom** key. The ROI (region of interest) box displays over the B-mode image. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view. ■ ***Display Zoom*** (From a Frozen Image): Press **Zoom** key. The image magnifies 1.5X Press Depth rocker key up to increase magnification Press Depth rocker key down to decrease magnification Use Trackball to pan the image. Press **Zoom** to return to the normal view **_mini_Cart:** ■ Press Zoom Touchscreen key. The ROI (region of interest) box displays over the B-mode image. Define the ROI: Use the trackball. Press Set to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view	■ Highlight **Zoom**. Press the **Select** key to activate Zoom. The ROI (region of interest) box displays over the B-mode image. The toggle icon is green when Zoom is active. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Select **Zoom** to display the enlarged ROI. Select **Zoom** to return to the normal view.
Disp Format*	■ Highlight **Disp Format** (display format). Press **Left / Right** function on **Menu Control** to select the preferred display formats. The available display formats are: • M-strip (frozen image) or scroll (live image) • Split-screen (B-mode image above and M-strip below), which has options for relative sizes of B-mode image and M-mode strip size	
Sweep Speed *	■ Highlight **Sweep Speed**. Press **Left / Right** function on **Menu Control** to select the preferred M-strip scroll rate (Low, Medium, High). The selected value displays to the left of the M-strip.	
Maps *	■ Highlight **Maps**. Press **Left / Right** function on **Menu Control** to select the desired tissue grey-scale map to be applied to the M-Mode sweep.	

M-Control	SuperCart & *mini*Cart	Scan Engine
Frequency SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Frequency** rocker key, press the **Up** to increase the transmit frequency; press the **Down** to decrease the transmit frequency for the M-Mode image. The selected value is displayed in the Image Information area. ***mini*Cart:** ■ From the Touchscreen, on the **MHz** key, press the Up Arrow to increase the transmit frequency, press the Down Arrow to decrease the transmit frequency. The selected value is displayed in the Image Information area.	■ Highlight **Frequency**. Press **Left / Right** function on **Menu Control** to increase / decrease the desired transmit frequency for the M-Mode image. The selected value displays in the Image Information area.
Dynamic Range ✱ 	■ Highlight **Dyn Range**. Press **Left / Right** function on **Menu Control** to select the preferred dynamic range processing setting.	
Persistence ✱ 	■ Highlight **Persistence**. Press **Left / Right** function on **Menu Control** to select the preferred level of M-mode line averaging.	
A Output 	■ Highlight **A Output**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired transmit power output level. The current transmit power level is displayed (as a percentage; 25%, 50%, etc.) in the Image Information area	
MIC SuperCart - n / a - Scan Engine -	■ Press the **MIC** button (in the center of the VOL control knob) to toggle on / off the active recording mode for the built-in microphone on the UI of the SuperCart. An ICON, in the shape of a microphone, is displayed on the screen when the MIC is active.	■ n / a.

Color and Power Doppler Imaging

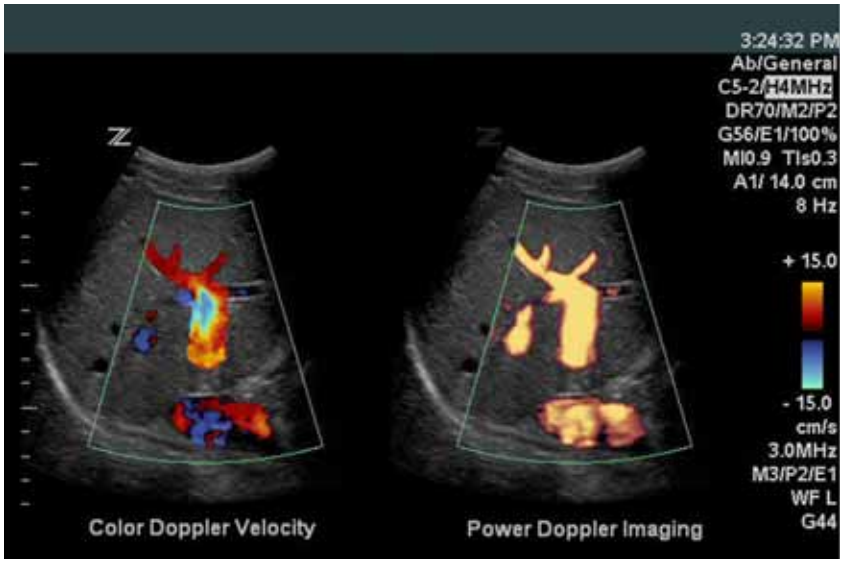
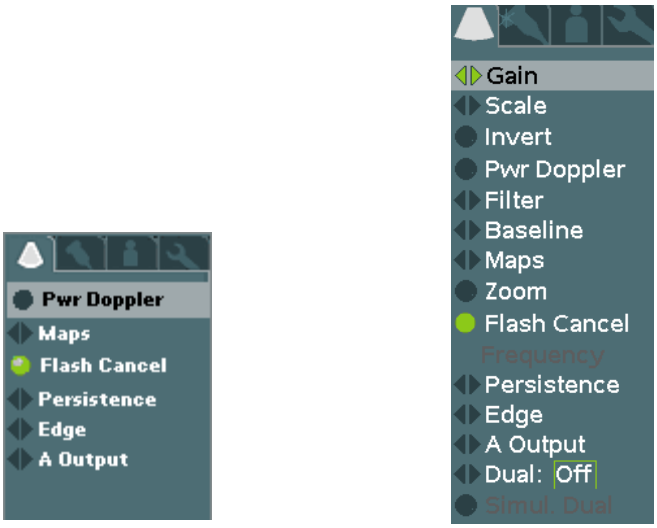


Figure 3-9. **Color Mode & Power Doppler Display Format**

Color Doppler provides qualitative directional information about blood flow (mean velocity) within the color region of interest (color ROI).

Power Doppler provides qualitative non-directional energy information about the blood flow within the Power Doppler ROI.

Color Doppler Menu (SuperCart & Scan Engine)



SuperCart Scan Engine

Figure 3-10. **Color Doppler Menu (Imaging Tab) - SuperCart & Scan Engine**

Color Doppler Touchscreen Menu - (*mini*Cart)

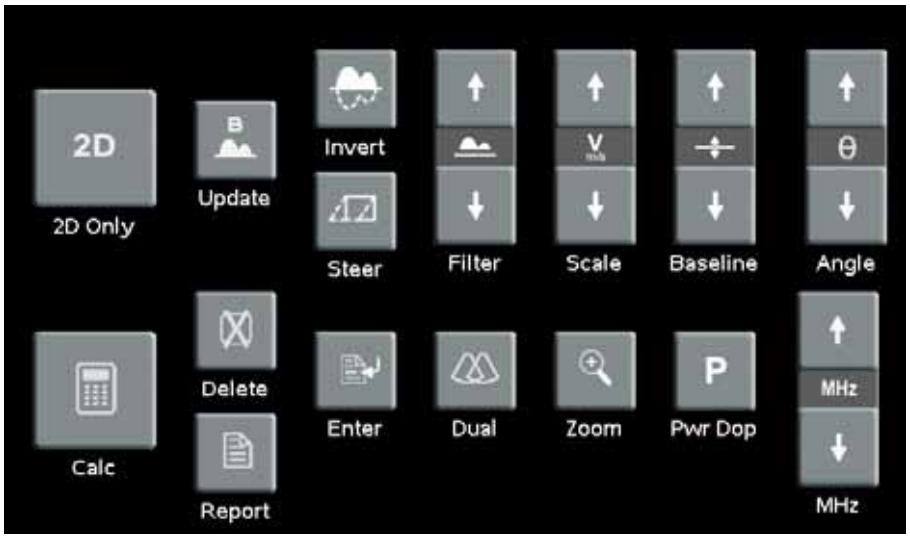


Figure 3-11. **Color Doppler Touchscreen Menu - *mini*Cart**

Working with Color and Power Doppler Imaging

1. Acquire the B-mode image. Refer to "B-mode Menu - (SuperCart & Scan Engine)" on page 3-12.
2. To initiate Color Doppler mode, do the following:

   Press **C**.

   Press **Menu control** to view the Color Doppler menu.

   An alternate method to initiate the Scan Engine is to press **Mode** to view the Mode menu. Select **Color Doppler**.

   The Color Mode status information and the Color Bar are displayed to the left of the image.
3. To define the color ROI, do the following:

   The color ROI can be redefined at any time on a live image.

   Use the trackball. Press **Set** to toggle between ROI Position and ROI Size.
4. To optimize the Color Doppler image, refer to "Color Doppler and Power Doppler Controls" on page 3-34.
5. To freeze the image, press **Freeze**. Refer to "Live and Frozen Images" on page 3-11.
6. To perform retrospective processing (optional), use the retrospective processing controls (available for a frozen image), which are denoted by ∗ in the Controls table.
7. To initiate Power Doppler mode (optional), do the following.

   Press **Freeze** to return to live imaging.

   Select **PWR Doppler** from the Color Doppler menu. The toggle icon is green when Power Doppler mode is active.

   The Power Doppler image can be frozen and retrospective processing can be performed on it in the same way as with the Color Doppler image.
8. To exit Power Doppler mode, press **Menu control** to view the Color Doppler menu. Select **PWR Doppler** to return to Color Doppler imaging.
9. To return to B-mode (optional), press **C**.

"DUAL" Imaging Mode - Introduction

Turning on the **DUAL** imaging function will cause the system to display two side-by-side images (referred to as image A and image B for the purpose of

this document). Only non-strip imaging modes (i.e. Color Doppler, or Power Doppler) are supported for DUAL image mode

In basic DUAL mode one of the two images displayed on the screen will be active (live updating) while the other image is static (not updating). DUAL mode (when in Doppler) allows for displaying a **Color Doppler** mode image side-by-side with a **Power Doppler** mode image of the same patient.

In addition to basic DUAL mode, a subset ***Simultaneous*** DUAL mode may be selected. In the ***Simultaneous*** DUAL mode both images (A and B) displayed on the screen will be dynamically active (live updating). During ***Simultaneous*** DUAL mode, one image will be selected as the "active" image (indicated by the "**Z**" Zonare logo). User controls are applied in the following manner during ***Simultaneous*** DUAL mode operation:

- **Pre-Processing** functions (A Output, C, etc.) - "ACTIVE" image only
- **Post-Processing** functions (Baseline, Filter, Maps) - BOTH images affected

"DUAL" Imaging Mode - Activation

1. To activate **DUAL** mode, do the following:

   SuperCart:
   – Press the **DUAL** key.

   ***mini*Cart:**
   – Press the **DUAL** softkey on the touchscreen.

   Scan Engine:
   – Using the **Menu Contro**l, scroll down to backlight the **Dual: Off** selection.

   – Using the **Left/Right** function of the **Menu Control**, toggle to the initial DUAL image (**A**)

2. Optimize the orientation on the patient's anatomy, user settings, and image quality, for the initial image displayed (**A**).

3. To toggle (activate) to the other DUAL image (**B**), do the following:

   SuperCart:
   – Press the shared-use **ENTER (Calc) /** (*DUAL:Toggle*) key.

   ***mini*Cart**:
   – Press the **ENTER** softkey on the touchscreen.

   Scan Engine:
   – Using the **Menu Contro**l, ensure that the backlight is selecting the **Dual** function.

– Using the **Left/Right** function of the **Menu Control**, toggle through to the activate the (**B**) DUAL image

4. Optimize the orientation on the patient's anatomy, user settings, and image quality, for this second image displayed (**B**).

Simultaneous DUAL Operation

1. While already in DUAL mode, to activate ***Simultaneous*** DUAL mode, do the following:

SuperCart:
– Press the shared-use **UPDATE** / **(***Simul-Dual***)** key.

***mini*Cart:**
– Press the shared-use UPDATE / (*Simul-Dual*) softkey on the touchscreen

Scan Engine:
– Using the **Menu Contro**l, scroll down to backlight the **Simul:Dual** selection.

– Press the **Enter** key (or use the **Left/Right** function of the **Menu Control**) to toggle On / Off ***Simultaneous*** DUAL imaging mode.

Color Doppler and Power Doppler Controls

✱ Indicates that this control is also available in retrospective processing.

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Gain ✱ SuperCart Scan Engine	**SuperCart:** ■ Adjust Gain using the **Gain** knob in the Doppler area. ***mini*Cart:** ■ Use the same method for the Scan Engine.	■ Adjust Gain using the **Gain** knob. ■ Highlight **Gain**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired receive gain. The selected value displays in the Image Information area.
Scale ✱ SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Scale** (velocity) rocker key, press the **Up** to increase the velocity scale; press the **Down** to decrease the velocity scale for the color map. The selected values display at the top and bottom of the Color Bar. ***mini*Cart:** ■ On the **Scale** (velocity) Touchscreen key, press the Up arrow to increase the velocity scale; press the Down arrow to decrease the velocity scale for the color map. The selected values display at the top and bottom of the Color Bar.	■ Highlight **Scale**. Press **Left / Right** function on **Menu Control** to increase / decrease the upper and lower velocity limits of the color map. The selected values display at the top and bottom of the Color Bar.

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Steer * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Steer** key to toggle to the desired steering orientation of the Color ROI (Right, Left, or Center). ■ **Steer** is available for linear array transducers only. **_mini_Cart:** ■ Press **Steer** Touchscreen key to toggle to the desired steering orientation of the Color ROI (Right, Left, or Center)	■ Highlight **Steer**. Press **Left / Right** function on **Menu Control** to toggle to the desired steering orientation of the Color ROI (Right, Left, or Center). **NOTE:** **Steer** *is available for linear array transducers only.*
Invert * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Invert** key to toggle the orientation of the color map (red / blue - towards / away **_mini_Cart:** ■ Press **Invert** Touchscreen key to the orientation of the color map (red / blue - towards / away blood flow.	■ Highlight **Invert**. Press the **Select** key to toggle the orientation of the color map (red / blue - towards / away blood flow).
Pwr Doppler SuperCart & Scan Engine *mini*Cart	**SuperCart:** ■ Highlight **Pwr Doppler** in the pop-up menu. Press **Select** to toggle between Color Doppler and Power Doppler modes. **_mini_Cart:** ■ Press **Pwr Dop** Touchscreen key to toggle between Color Doppler and Power Doppler modes.	■ Highlight **Pwr Doppler**. Press the **Select** key to toggle between Color Doppler and Power Doppler modes.

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Filter * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Filter** rocker key, press the **Up** key to increase the filter; press the **Down** key to decrease the filter. The selected value (Low, Medium, High) displays in the Color Doppler Status area. **_mini_Cart:** ■ On the **Filter** Touchscreen key, press the Up arrow to increase the filter; press the Down arrow to decrease the filter. The selected value (Low, Medium, High) displays in the Color Doppler Status area.	■ Highlight **Filter**. Press **Left / Right** function on **Menu Control** to increase or decrease the filter. The selected value (Low, Medium, High) displays in the Color Doppler Status area.
Baseline * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Baseline** rocker key, press the **Up** key or the **Down** key to shift the Color Bar baseline. The velocity to color assignment values change as the baseline shifts. **_mini_Cart:** ■ On the **Baseline** Touchscreen key, press the Up arrow or the Down arrow to shift the Color Bar baseline. The velocity to color assignment values change as the baseline shifts.	■ Highlight **Baseline**. Press **Left / Right** function on **Menu Control** to shift the Color Bar baseline up or down. The velocity to color assignment values change as the baseline shifts.
Maps *	■ Highlight **Maps**. Press **Left / Right** function on **Menu Control** to choose the preferred Color map for the Color Doppler or Power Doppler display.	

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Zoom SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Zoom** key. The zoom ROI (region of interest) box displays around the color ROI. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view. ***mini*Cart:** ■ Press **Zoom** Touchscreen key. The zoom ROI (region of interest) box displays around the color ROI. Define the ROI: Use the trackball. Press Set to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view	■ Highlight **Zoom**. Press the **Select** key to activate Zoom. The Zoom ROI (region of interest) box displays around the color ROI. The toggle icon is green when Zoom is active. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Select **Zoom** to display the enlarged ROI. Select **Zoom** to return to the normal view. **NOTE:** When frozen, Zoom will activate Display Zoom
Flash Cancel*	■ Highlight **Flash Cancel**. Press **Select** key to toggle On / Off this function. When **Flash Cancel** is deselected (the default setting) this function provides a filtering of the flash artifact caused by the low velocity / high amplitude signals produced by moving tissue structures.	
Frequency * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Frequency** rocker key, press the **Up** key or the **Down** key to increase or decrease the transmit frequency for the Color / Power Doppler. The current frequency is displayed in the Image Information area. ***mini*Cart:** ■ On the **Frequency** Touchscreen key, press the Up arrow or the Down arrow to increase or decrease the transmit frequency for the Color / Power Doppler. The current frequency is displayed in the Image Information area.	■ Highlight **Frequency**. Press **Left / Right** function on **Menu Control** to increase or decrease the transmit frequency for the Color / Power Doppler. The current frequency is displayed in the Image Information area.

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Persistence *	■ Highlight **Persistence**. Press **Left / Right** function on **Menu Control** to change the level of frame averaging.	
Edge *	■ Highlight **Edge**. Press **Left / Right** function on **Menu Control** to change to the desired image edge enhancement option.	
A Output	■ Highlight **A Output**. Press **Left / Right** function on **Menu Control** to increase or decrease the transmit power output level. The current transmit power level is displayed (as a percentage; 25%, 50%, etc.) in the Image Information area. **NOTE:** Minimum is a power level of 25%	
Dual: Off/On SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the key labeled **DUAL** to toggle the Dual imaging function On / Off. **NOTE:** The **Dual** imaging function allows for displaying two separate images on the screen (at the same time), for concurrent comparison / analysis. ***mini*Cart:** ■ Press the Touchscreen key labeled **DUAL** to toggle the Dual imaging function On / Off.	Highlight Dual. Press Select key to toggle On / Off this function.
Dual: Toggle SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the shared use **Enter (Calc)/Dual Toggle** key to change the selection of the"Active" / "Selected" image (Left or Right image, as displayed on screen). ***mini*Cart:** ■ Press the Touchscreen key labeled **Enter (Calc)** / Dual Toggle key to change the selection of the"Active" / "Selected" image (Left or Right image, as displayed on screen).	Highlight **Dual Off (On)**. Pressing the **Left / Right** function on **Menu Control** will sequence through four (A, B, A:b, a:B) different **Dual** image display states. > A:b = Left image active / Right image static > a:B = Left image static / Right image active > A = Full sized Left image displayed > B = Full sized Right image displayed

CD / PD Control	SuperCart & *mini*Cart	Scan Engine
Simul: (Dual) SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press the shared use **Update** / Simul key to toggle On / Off the Simultaneous Dual imaging update modality. **NOTE:** When Simul Dual is active, the two different images, potentially using different modalities (i.e. Color Doppler & Power Doppler) will be dynamically updated, simultaneously. **NOTE:** When this function is deselected (standard Dual mode) one image will be static, while the other image is dynamically active. ***mini*Cart:** ■ Press the Touchscreen **B Update** softkey (Update / Simul Dual Toggle) to toggle On / Off the **Simultaneous** Dual imaging update modality.	■ Highlight **Simul: Dual.** Press **Select** to toggle On / Off this function. **NOTE:** When **Simul Dual** is active, the two different images, potentially using different modalities (i.e. Color Doppler & Power Doppler) will be dynamically updated, simultaneously. When this function is *deselected* (standard Dual mode) one image will be static, while the other image is dynamically active.
MIC SuperCart - n / a - Scan Engine	■ Press the **MIC** button (in the center of the VOL control knob) to toggle on / off the active recording mode for the built-in microphone on the UI of the SuperCart. An ICON, in the shape of a microphone, is displayed on the screen when the MIC is active.	■ n / a.

Pulse Wave (PW) Doppler Imaging

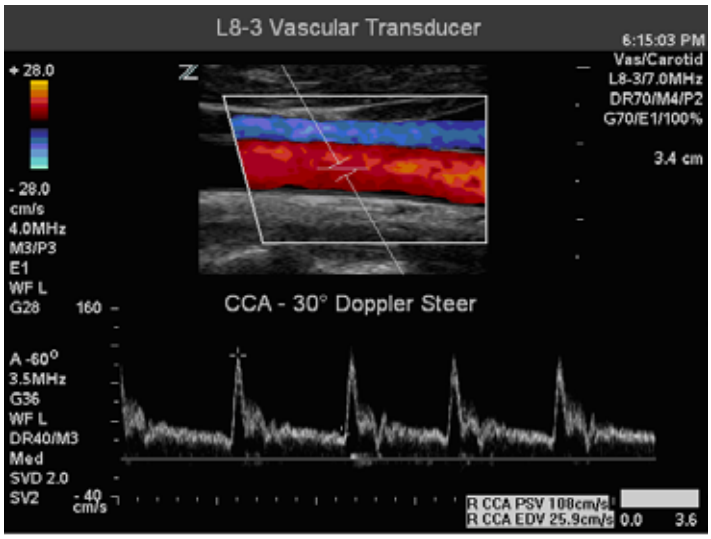


Figure 3-12. **Pulse Wave (PW) Doppler Image**

Pulse Wave (PW) Doppler is used to assess blood flow velocity.

Working with PW Doppler Imaging

1. Acquire the B-mode image. Refer to "B-mode Menu - (SuperCart & Scan Engine)" on page 3-12.

2. To initiate Pulse Wave (PW) Doppler imaging, do the following:

   Press **PW**.

   Press **Menu control** to view the PW Doppler menu.

   An alternate method to initiate the Scan Engine is to press **Mode** to view the Mode menu. Select **PW-mode**.

   Press **Menu control** to view the PW Doppler menu.

   The PW cursor bisects the image. The PW scroll begins. The PW-mode status information displays to the left of the PW strip.

3. To position the PW cursor, do the following:

   Position the PW cursor left and right using the trackball.

4. To define the gate, do the following:

   SuperCart: Select **Gate Size**. Use the Menu control's **Left** and **Right** keys to adjust the size of the gate.

Scan Engine: Select **Gate Size**. Use the Menu control's **Left** and **Right** keys to adjust the size of the gate.

Press **Select** or **Back** to save the setting and return to the menu.

5. To steer the PW cursor, adjust the angle correction, or optimize the PW Doppler image, refer to the following table. Steer is available for linear array transducers only.
6. To freeze the image, press **Freeze**.
7. To perform retrospective processing (optional), use the retrospective processing controls (available for a frozen image), which are denoted by ∗ in the Controls table.
8. To return to B-mode (optional), press **PW**.

PW Doppler Controls

✱ Indicates that this control is also available in retrospective processing

PW Control	SuperCart & *mini*Cart	Scan Engine
Gain ✱ SuperCart Scan Engine	**SuperCart:** ■ Adjust Gain using the **Gain** knob in the Doppler control area. The selected value displays in the PW Doppler Status area. ***mini*Cart:** ■ Use the same method for the Scan Engine.	■ Adjust gain using the **Gain** knob. ■ Select **Gain**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired gain of the Doppler spectrum. The selected value displays in the PW Doppler Status area.
Scale ✱ SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Scale** (velocity) rocker key, press the **Up** key to increase the velocity scale; press the **Down** key to decrease the velocity scale. The selected values displays in the PW Doppler Status area. ***mini*Cart:** ■ On the **Scale** (velocity) Touchscreen key, press the Up arrow to increase the velocity scale; press the Down arrow to decrease the velocity scale. The selected values displays in the PW Doppler Status area.	■ Highlight **Scale**. Press **Left / Right** function on **Menu Control** to change the velocity scale for PW Doppler. The selected values displays in the PW Doppler Status area.

PW Control	SuperCart & *mini*Cart	Scan Engine
Baseline * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the Baseline rocker key, press the **Up** key or the **Down** key to shift the Doppler spectrum baseline. The velocity values increase and decrease as the baseline shifts. ***mini*Cart:** ■ On the **Baseline** Touchscreen key, press the Up arrow or the Down arrow to shift the Doppler spectrum baseline. The velocity values increase and decrease as the baseline shifts.	■ Select **Baseline**. Press **Left / Right** function on **Menu Control** to shift the Doppler spectrum baseline. The velocity values increase and decrease as the baseline shifts.
Invert * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Invert** key to flip the blood flow direction vs. strip display orientation, in the Doppler spectrum. ***mini*Cart:** ■ Press **Invert** Touchscreen key to flip the blood flow direction vs. strip display orientation, in the Doppler spectrum.	■ Highlight **Invert**. Press Select key to flip the blood flow direction vs. strip display orientation, in the Doppler spectrum.

PW Control	SuperCart & *mini*Cart	Scan Engine
Update * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Update** key to toggle between live update of the B-Mode image concurrent with live PW Doppler spectrum, or frozen B-Mode image with live Doppler spectrum. ***mini*Cart:** ■ Press **Update** Touchscreen key to toggle between live update of the B-Mode image concurrent with live PW Doppler spectrum, or frozen B-Mode image with live Doppler spectrum.	■ Highlight **Update**. Press **Select** key to toggle between live update of the B-Mode image concurrent with live PW Doppler spectrum, or frozen B-Mode image with live Doppler spectrum.
Angle Correct* SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Quick 60: Push the **Angle Control** knob to adjust the angle in 60° increments (-60°, 0, +60°). 1° increments: Turn the Angle Control knob clockwise to increase the angle; turn counter clockwise to decrease the angle. The selected value displays in the PW Doppler Status area. ***mini*Cart:** ■ On the **Angle Correct** key on the Touchscreen, press Up / Down Arrows to adjust the angle in 1 increments.	Highlight **Angle**. Quick 60: Press **Select** to adjust the angle in 60° large increments (-60°, 0, +60°). Fine 1: Press **Left / Right** function on **Menu Control** to adjust the angle in 1° increments. The selected values displays in the PW Doppler Status area.

PW Control	SuperCart & *mini*Cart	Scan Engine
Steer * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Steer** to steer the PW cursor to the right, left, or center. L8-3 Transducer: two steering angles are available, (30 ° and 20 °). From the Doppler menu, highlight PW angle. Press Left / Right function on Menu Control to toggle between 30 ° and 20 °. **NOTE:** Steer is available for linear array transducers only. ***mini*Cart:** ■ Press **Steer** Touchscreen key to toggle to the desired steering orientation (Right, Left, or Center).	■ Highlight **Steer**. Press **Left / Right** function on **Menu Control** to toggle to the desired steering orientation of the Color ROI (Right, Left, or Center). L8-3 Transducer: two steering angles are available, (30 ° and 20 °). From the Doppler menu, highlight PW angle. Press Left / Right function on Menu Control to toggle between 30 ° and 20 °. **NOTE:** Steer is available for linear array transducers only.
Filter * SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ On the **Filter** rocker key, press the **Up** key to increase the filter; press the **Down** key to decrease the filter. The selected value (Low, Medium, High) displays in the PW Doppler Status area. ***mini*Cart:** ■ On the **Filter** Touchscreen key, press the Up arrow to increase the filter; press the Down arrow to decrease the filter. The selected value (Low, Medium, High) displays in the PW Doppler Status area.	■ Highlight **Filter**. Press **Left / Right** function on **Menu Control** to increase or decrease the filter. The selected value (Low, Medium, High) displays in the PW Doppler Status area.
Gate Size	Highlight **Gate Size**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired range gate size.	Highlight **Gate Size**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired range gate size.

PW Control	SuperCart & *mini*Cart	Scan Engine
Dynamic Range ✱	■ Highlight **Dyn Range**. Press **Left / Right** function on **Menu Control** to adjust the dynamic range setting.	
Sweep Speed ✱	■ Highlight **Sweep Speed**. The speed of the PW-strip scroll changes. Press **Left / Right** function on **Menu Control** to choose the sweep rate selection (Low, Medium, High). The selected value displays to the left of the PW-strip.	
Disp Format✱	■ Highlight **Disp Format** (display format). Press **Left / Right** function on **Menu Control** to choose the preferred display format. The available display formats are: • PW-strip (frozen image) or scroll (live image) • Split-screen (B-mode image above and PW-strip below), which has options for relative sizes of B-mode image and PW-mode strip size	
Maps ✱	■ Highlight **Maps**. Press **Left / Right** function on **Menu Control** to choose the preferred grey-scale maps (M1, M2, M3, M4) to be used in the spectral Doppler.	
Zoom SuperCart Scan Engine *mini*Cart	**SuperCart:** ■ Press **Zoom** key. The ROI (region of interest) box displays around the PW gate in the image. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view. ***mini*Cart:** ■ Press **Zoom** Touchscreen key. The zoom ROI (region of interest) box displays around the PW gate in the image. Define the ROI: Use the trackball. Press Set to toggle between ROI position and ROI size. Press **Zoom** to display the enlarged ROI. Press **Zoom** to return to the normal view	■ Select **Zoom**. Press the **Select** key to enable the Zoom function. The ROI (region of interest) box displays around the PW gate in the image. The toggle icon is green when Zoom is active. Define the ROI: Use the trackball. Press **Set** to toggle between ROI position and ROI size. Select **Zoom** to display the enlarged ROI. Select **Zoom** to return to the normal view.
A Output	■ Highlight **A Output**. Press **Left / Right** function on **Menu Control** to increase or decrease the desired transmit power output level selected. The current transmit power level is displayed (as a percentage; 25%, 50%, etc.) in the Image Information area	

PW Control	SuperCart & *mini*Cart	Scan Engine
CD Processing	■ Highlight **CD Processing** Pressing **Select** will exit the PW mode controls, and bring the Color Doppler Processing controls into the main menu, to allow for making adjustments to the Color Doppler image.	
Audio (Vol) SuperCart Scan Engine - Use touchscreen controls	■ Use the **Volume** knob to increase and decrease audio volume.	■ Using the stylus, activate the Audio control on the touchscreen bezel.
MIC SuperCart - n / a - Scan Engine -	■ Press the **MIC** button (in the center of the VOL control knob) to toggle on / off the active recording mode for the built-in microphone on the UI of the SuperCart. An ICON, in the shape of a microphone, is displayed on the screen when the MIC is active.	■ n / a.

Duplex Mode

In Duplex mode (B-Mode and PW-mode running simultaneously) an available **Update** option pauses either the 2D image display or the scrolling PW strip.

To turn on the Update option

1. Select the **Update** key in the Doppler controls (SuperCart), or scroll down to the **Update** selection on the Doppler menu (Scan Engine) and select.

   Use the **Set** key to toggle between pausing the 2D image display and the scrolling PW strip.

To turn off the Update option

1. To return to simultaneous mode, deselect the **Update** key (SuperCart), or deselect the **Update** selection (Scan Engine) on the Doppler menu.

Triplex Mode

Triplex mode allows the user to visualize B-mode, Color or Power Doppler, and PW Doppler modes simultaneously. As with Duplex mode, an available Update option pauses either the 2D image display (B and Color) or the scrolling PW strip. The Update On / Off control is the same as for the Duplex mode.

4

Annotations

The user can enter text annotation and body pattern graphics on live images, frozen images, stored images during in-progress exam review (open exam), and stored images from restarted exams. Arrow graphics can be entered on frozen images, stored images during in-progress review (open exam), and stored images from restarted exams.

Annotations and graphics can be stored with the frozen image in the open exam, with stored images during in-progress exam review, and with stored images from restarted exams.

Annotations and graphics can be intermixed and placed on the image in any order.

Figure 4-1. **Annotation Keys**

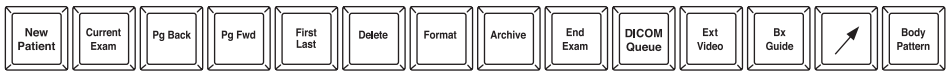


Figure 4-2. **Top Row of the Keyboard (SuperCart or *mini*Cart) Keys**

Annotation Types

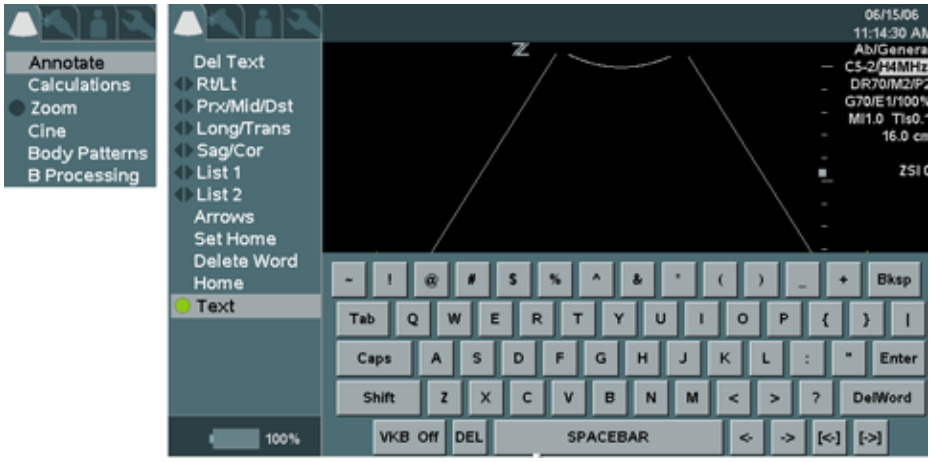


Figure 4-3. **Text Menu & Virtual Keyboard (Scan Engine)**

Three types of text annotation and two types of graphics can be placed on the image.

Free-form Text

Free-form text can be entered from the SuperCart (or *mini*Cart) keyboard or from the Scan Engine virtual keyboard (VKB). Free-form text can be placed anywhere on the screen except for the image title bar and the menu area.

Programmed Orientation Text (POT)

Three sets of programmed orientation text (POT) values can be placed on the image:

- Longitudinal / Transverse / Sagittal / Coronal
- Right / Left
- Proximal / Mid / Distal

POTs can be placed anywhere on the screen except for the image title bar and the menu area.

List Text Entries

List 1 and List 2 menus are application-specific terms defined by the user. List entries can be placed anywhere on the screen except for the image title bar and the menu area.

Arrow Graphic

The arrow is free moving and can be placed anywhere on the screen except for the image title bar and the menu area. As many as 15 arrows can be placed on the image.

Body Pattern Graphics

One Body Pattern graphic can be placed from an Exam Type-specific Body Patterns menu. The selected graphic is displayed in the lower-left quadrant of the image area. After the Body Pattern graphic is placed, use the trackball and the **Set** key to position and rotate the transducer graphic.

Annotation Procedures

To place annotations (SuperCart or *mini*Cart)

1. Press the **Text** key or **Spacebar** on the keyboard.

   The green text cursor appears at the default Home position.

2. Use the trackball to move the text cursor to another position.

   Annotations can now be entered at the cursor position.

3. Press the **Home** key on the keyboard to move the text cursor to the Home position at any time.

4. To redefine the Home position, use the trackball to move the text cursor to the desired Home position.

   Press **Shift + Set Home** on the keyboard. This position is now defined as the new Home position, and then the text cursor moves to that position when the **Home** key is pressed.

NOTE: The user can enter POT values without first pressing the **Text** key. When a POT key is pressed and no text cursor is displayed, the POT is entered at the Home position or at the last text cursor position if text was previously invoked. The text cursor displays to the right of the POT value.

To place annotations (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the Text menu item, and then press the **Select** key.

   The green text cursor appears at the default Home position. Scroll to the keyboard, and then press the **Select** key to activate the VKB displays.

2. Use the trackball to move the text cursor to another position. Annotations can now be entered at the cursor position.
3. Use the Menu Control to scroll to the Home menu item, and then press the **Select** key to move the text cursor to the Home position at any time.
4. To redefine the Home position, use the trackball to move the text cursor to the desired Home position.

   Use the Menu Control to scroll to the Set Home menu item, and then press the **Select** key. This position is now defined as the new Home position, and then the text cursor moves to that position when the Home menu item is selected.

To enter annotations (SuperCart or *mini*Cart)

1. Press the **Text** key or **Spacebar** on the keyboard to display the text cursor.
2. Use the trackball to move the text cursor to the desired position.
3. Use the keyboard to enter the desired text. Enter a character to place that character at the cursor location, and then move the cursor one character to the right.

   The keyboard defaults to uppercase.
4. Use the trackball to move the text cursor to another position, and then continue entering text.

NOTE: POT values can be entered without first pressing the **Text** key. When a POT key is pressed and no text cursor is displayed, the POT is entered at the Home position or at the last text cursor position if text was previously invoked. The text cursor displays to the right of the POT value.

To enter programmed orientation text (POT) (SuperCart or *mini*Cart)

1. Press the **Text** key on the keyboard to display the text cursor.
2. Use the trackball to move the text cursor to the desired position.
3. Press one of the POT keys on the keyboard.

   The first POT value display, and then the text cursor moves to the right of the displayed value.

   The POT keys are cycling keys. Press a POT key to replace the currently displayed value with the next value.
4. Continue pressing a POT key until the desired value is displayed.

   Press another POT key to place its value to the right of the first POT entry.

NOTE: POT values can be entered without first pressing the **Text** key. When a **POT** key is pressed and no text cursor is displayed, the POT is entered at the Home position or at the last text cursor position if text was previously invoked. The text cursor displays to the right of the POT value.

To enter list text (SuperCart or *mini*Cart)

1. Press the **Text** key on the keyboard to display the text cursor.
2. Use the trackball to move the text cursor to the desired position.
3. Press the List1 key on the keyboard.

   The first list value displays, and then the text cursor moves to the right of the displayed value.

   The List key is a cycling key, each press replacing the currently displayed value with the next value.
4. Continue pressing the List1 key until the desired value is displayed.

   Press **Shift + List2** to place the first value in List 2 to the right of the last text entry.

   List1/2 values can be entered without first pressing the **Text** key. When the List1/2 key is pressed and no text cursor is displayed, the List1 or List2 value is entered at the Home position or at the last text cursor position if Text had been previously invoked. The text cursor displays to the right of the List1/2 value.

To enter annotations (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the Annotate menu item, and then press the **Select** key to display the text cursor. To enter free text, scroll to the keyboard, and then press the **Select** key to activate the VKB.
2. Use the trackball to move the text cursor to another position. Annotations can now be entered at the cursor position.
3. Use the stylus on the VKB to enter the desired text.

   Enter a character to place that character at the cursor location, and then move the cursor one character to the right. The VKB defaults to uppercase.

4. Use the trackball to move the text cursor to another position, and then continue entering text.

To enter programmed orientation text (POT) (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the Annotate menu item, and then press the **Select** key to display the text cursor.
2. Use the trackball to move the text cursor to the desired position.
3. Use the Menu Control to scroll to one of the POT menu items, and then press the **Select** key.

   The first POT value displays, and then the text cursor moves to the right of the displayed value.

   The POT keys are cycling keys. Press a POT key to recycle the currently displayed value with the next value.
4. Continue selecting a POT key until the desired value is displayed.

   Select another POT key to place its value to the right of the first POT entry.

To list text (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the Annotate menu item, and then press the **Select** key to display the text cursor.
2. Use the trackball to move the text cursor to the desired position.
3. Use the Menu Control to scroll to List1 and press the **Select** key.

   The first list value displays, and then the text cursor moves to the right of the displayed value.

   The List key is a cycling key. Press each key to recycle the currently displayed value with the next value.
4. Continue selecting the List1 key until the desired value is displayed.

   Select List2 to place the first value in List2 to the right of the last text entry.

   List1 and 2 values can be entered without first pressing the **Text** key. When the List1 or List2 menu items are selected and no text cursor is displayed, the List1 or List2 value is entered at the Home position or at the last text cursor position if Text had been previously invoked. The text cursor displays to the right of the List1 or List 2 value.

To exit annotations (SuperCart or *mini*Cart)

When the user exits Annotations mode, the text cursor is removed. Take the following steps to exit Annotations mode.

1. Press the **Text** key on the keyboard.
2. Freeze the image.
3. Unfreeze the image.

   The **z.one** remembers the last cursor position, and then the cursor defaults to the previous position when annotation mode is entered the next time.

To exit annotations (Scan Engine)

When the user exits Annotations mode, the text cursor is removed. Take the following steps to exit Annotations mode.

1. Press the **Back** key.
2. Freeze the image.
3. Unfreeze the image.

   The **z.one** remembers the last cursor position, and then the cursor defaults to the previous position when Annotation mode is entered the next time.

Working with Annotations

A single text annotation is limited to six lines or the number of lines that will fit before replacing the bottom of the imaging area, whichever comes first. Characters are never “chopped off” at the right edge of the screen; when the cursor reaches the right edge of the screen, the **z.one** automatically performs a carriage return and aligns the cursor with the left most character of the free text string. If the **z.one** reaches the point where entering another character results in text extending beyond the bottom of the screen, any subsequent keyboard character keystrokes are ignored.

Use the **Backspace** key to delete the character to the left of the cursor and shift the characters to the right of the cursor one character to the left.

When the cursor moves to a new position after the user enters text, that text string is considered “complete.” That is, the cursor cannot be moved back into the string and text entry continue. If the cursor moves into another string, any existing text entry displays on top of what is currently entered.

POTS and Lists

There can be up to three POT entries (one for each key) and two list entries on a line. Regardless of the ordering of the entries, if a POT string was entered, subsequent presses of a POT key or selection of a POT menu item cycles the POT values, even if other POT and list entries have been placed there after it. For example if POT and list entries have been made such that the display shows that the COR LEFT PROX LIST1 and the **Rt/Lt** key are pressed, the display now shows COR RIGHT PROX LIST1. If the **Prox/Mid/Dist** key is pressed, the display shows COR RIGHT MID LIST1.

If the cursor position is changed after POT values were entered, subsequent key presses or menu item selections affect only strings at the new cursor position.

If a POT or list value is added in a line of text, the POT or list value is entered with a space after it.

Delete Word and Delete Text Behavior

When the user presses **Shift + Delete Word** on the Super Cart keyboard or selects **Del Word** from Scan Engine menu, the most recently typed or POT word is deleted. Press **Delete Word** when the text cursor displays to move the text cursor to the Home position.

Press **Delete Text** to delete all text, POT and List values displayed. This also deletes any arrow graphics on a frozen image. Pressing **Delete Word** does not delete any Body Pattern graphics. Press **Delete Word** when the text cursor does not display to delete all text, POT and List values and the text cursor does not display.

Insert Mode and Overwrite Mode Text Behavior

When there is typed Text, the user can either Insert or Overwrite between characters.

Insert Mode:

1. Place the Text cursor between the desired characters to start the insertion mode.
2. Press the Set key. Set key will toggle between Insert Mode and Overwrite Mode.
3. Toggle to Insert Mode. When typing, the characters to the right of the cursor will move to the right

Overwrite Mode:

1. Place the Text cursor between the desired characters to start the overwrite mode.
2. Press the Set key. Set key will toggle between Insert Mode and Overwrite Mode.
3. Toggle to Overwrite Mode. When typing, the characters to the right of the cursor will be replaced by the new characters.

Working with Graphics

To activate display of body patterns (SuperCart or *mini*Cart)

1. Press the **Body Pattern** key on the Super Cart keyboard.

   NOTE: The Body Pattern key is a toggle ON / OFF function

   An initial default Body Pattern specific to the Exam Type in use will appear at the bottom of the display.

To activate display of body patterns (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the **Body Patterns** menu item, and then press the **Select** key.

   An initial default Body Pattern specific to the Exam Type in use will appear at the bottom of the display.

To change body patterns (SuperCart or *mini*Cart)

1. Use the Left/Right arrows of the Menu Control to sequence through the available body patterns, until the desired pattern is displayed.

To change body patterns (Scan Engine)

1. From the Tools Tab menu or the Freeze menu, use the Menu Control to scroll to the **Body Patterns** menu item, and then press the **Select** key.
2. Ensure the **Pattern** menu item is selected in the Body Patterns menu.
3. Use the Left/Right arrows of the Menu Control to sequence through the available body patterns, until the desired pattern is displayed.

To position probe graphic (SuperCart, *mini*Cart, or Scan Engine)

In addition to the selected body pattern, a probe (transducer) graphic will be displayed in green (within the body marker). The message "Probe graphic positioning…" also displays.

1. Use the trackball to position the probe graphic.
2. When the probe graphic is positioned correctly, press the **Set** key.

   The probe graphic position locks and a message "Probe graphic rotating" displays.
3. Use the trackball to rotate the probe graphic.
4. When the probe graphic is correctly rotated, press the **Freeze** key.

   This locks the probe graphic and exit Body Patterns. The probe graphic now displays in white, and no messages display.

To remove body patterns from display (SuperCart or *mini*Cart)

1. To remove the Body Pattern graphic, press the **Body Pattern** key a second time.

   The Body Pattern is removed.

To remove body patterns from display (Scan Engine)

1. Use the left/Right arrows of the Menu Control to scroll to **Body Patterns** and press the **Select** key.
2. Use the Menu Control to scroll to menu item listed as **Blank**.
3. To remove the Body Pattern graphic, press the **Select** key.

   The Body Pattern is removed.

To use arrows (SuperCart or *mini*Cart)

1. Arrows can be used during live or frozen imaging.
2. Press the key on the keyboard. A green arrow displays in the center of the imaging area.
3. Use the trackball to position the arrow.

   If the key is pressed while an arrow is green, that arrow is removed.

   Pressing the key does not remove any arrows that have previously been locked in position.
4. Press the **Set** key to lock the arrow in position. The arrow turns white.
5. To display another arrow, press the key.

   As many as 15 arrows can be displayed at one time.
6. Exit freeze to remove all arrow graphics.

To use arrows (Scan Engine)

1. Arrows can be used during live or frozen imaging.
2. From the Toolbar menu, ensure that the Annotate menu item is highlighted, and then press the **Select** key.
3. Use the Menu Control to scroll to the Arrows menu item, and then press the **Select** key.

   A green arrow displays in the center of the imaging area.

4. Use the trackball to position the arrow.
5. Press the **Set** key to lock the arrow in position. The arrow turns white.
6. To display another arrow, press the **Select** key while the Arrows menu item is highlighted.

   As many as 15 arrows can be displayed at one time.

   If the key is pressed while an arrow is green, that arrow is locked in position
7. Exit freeze to remove all arrow graphics.

To clear all annotations and arrows

1. Press the Delete Text key to remove all Text and Arrows

To clear all annotations, arrows, and body marker

1. Start a New patient from the Patient Information page.
2. Change Exam Types.
3. Power off the **z.one**

5

Measurements and Calculations

Introduction to Measurements and Calculations

With the **z.one**, the user can perform a full range of measurements and calculations on live, frozen, and stored images from an open exam and on stored images from an archived exam.

Each imaging mode supports a specific set of a mode-dependent Generic Measurement Package. Only the measurements available for the active imaging mode are listed in the Measurement menu.

A Calculation Package can only be invoked when the user selects the associated Exam Type. If the selected Exam Type does not have an associated Calculation Package, then the **z.one** ignores any attempt to invoke a Calculation Package.

Measurement and calculation packages are customizable to allow for variations in demographic and workflow requirements.

Exam Types and Measurement Menus

The imaging mode determines the types of Generic Measurements that are available.

B-mode	M-mode	PW-mode
B Depth*	M Depth*	Velocity
B Distance	M Distance	RI
Circ / Area	HR	PI
Volume		Accel
% Stenosis		S / D
		A / B
		HR

*Note: A single B or M Distance Caliper measures Depth.

Additionally, a single caliper during live imaging measures depth when in B / M modes and Velocity when in Color / PW modes.

Calculation Packages

Figure 5-1. **Calculation menus**

Calculation packages have been developed for the **z.one** for the following Exam Types:

- OB

- GYN
- Vascular
- Abdomen

NOTE: If the Exam Type selected is a type that does not have a calculation package available (e.g. Small Parts) selecting the Calculation button in the control menu will have no effect (no Calc menu will be displayed).

The Exam Type determines the version of Calculation Package that will be offered. The combination of the Presets selection and imaging mode determine which of the supported Calculations Package measurements will be available and displayed in the Calculations Menu.

Worksheets and Reports

Each Calculation Package includes associated Worksheet and Report displays. All completed measurement results and any dependent calculation results are automatically populated to the Worksheet / Report for the selected Calculations package.

The Worksheet is essentially a spreadsheet that displays all of the measurement and calculation results entered into a Calculation Package, including multiple results for each measurement. Depending on the selected Calculation Package, the Worksheet can be edited to customize aspects of the display, select alternate equations, and edit measurement data.

The Report is the summary of the measurement and calculation results entered into a Calculations Package. The Report displays an abbreviated form of the content derived from the Worksheet. The Report is not directly editable, so the user must make any desired changes to the Worksheet. Changes made in the Worksheet will be reflected in the Report at its next selection.

All measurement and calculation results entered in a Calculation Package are saved when an image is stored (at least one image store is required) or the exam is ended. The Report for an exam which has been ended can be selected and reviewed using Archive Review.

The user can obtain hardcopy output of the Worksheet and / or Report displays by printing to a video printer connected to the SuperCart or sending the Worksheet to a network printer, using the DICOM print function.

Editing the Worksheet

Worksheet data fields are editable. The user can edit or delete existing results, and enter new results into any data fields. To navigate the Worksheet displays, the user uses either the Tab Key on the keyboard (or the virtual keyboard on the undocked Scan Engine) or uses the trackball / cursor followed by the Set button to select a data field. Once an editable field is selected, the user can enter or change data.

Selecting between the Worksheet and the Report displays

When the Scanner is docked in the SuperCart or *mini*Cart, all Worksheet pages include a soft button labeled Report. When the user selects the Report soft button on the Worksheet, the display toggles (switches) to a page of the Report display. Correspondingly, all Report pages include a soft button labeled Worksheet; and if the user selects the Worksheet soft button on the Report, the display toggles to the corresponding page of the Worksheet display.

When the Scanner is undocked, selecting the cycling option in the Calculations Menu performs the same function as the Worksheet and Report soft button when the Scanner is docked in the SuperCart / *mini*Cart.

Customizing Calc Packages

The Generic Measurement Configuration Package and the Calculation Configuration Package are accessed through the Calc menu. To access the selections, the user presses the Tab button until the Tools Tab is displayed and then selects Sys Setup from the Tools menu, and then the user selects Calcs from the Sys Setup menu.

The Calcs menu contains the following selections:

- General
- OB
- GYN
- Abdomen
- Pediatric Hip Angle
- Custom

The General selection displays the Generic Measurement Package. The user can customize the Caliper Connecting line behavior, the Percent Stenosis Method, and the Area Method.

These settings apply to the Generic Measurement Package, as well as the Calculation Packages, to the extent that they do not conflict with any specific tool behaviors for a Calc Package.

Tools for Measurements and Calculations

Freeze Menu

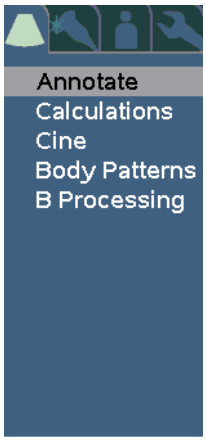


Figure 5-2. **Freeze Menu on the Scan Engine**

The image must be frozen before most measurements and calculations functions can be performed on it.

Measure Menu

The user can directly access the generic measurements via the measurement keys on the SuperCart and Scan Engine. The user can directly access exam specific calculations via the SuperCart and Scan Engine.

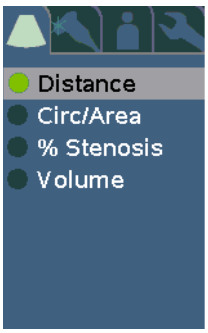


Figure 5-3. **Measure Menu**

Measurements and calculations that are available during the examination (mode specific) are listed in the measure menu. To select the appropriate item,

use the up / down arrow on the menu control, which automatically initializes the measurement and places a cursor on the imaging screen.

Fetus A, B, C, D, E

The OB calc package can be used to collect data on up to five fetuses, labeled Fetus A, B, C, etc. The Worksheet automatically reflects the number of fetuses recorded in the Patient Information form. Measurement data is recorded separately in the Worksheet for each selected fetus.

Right/Left

The **Right/Left** option is offered in the Measure menu for the Vascular and GYN and Abdomen. Toggle to record bilateral measurements.

CCA and ICA

The Measure menu for the Vascular Exam type includes **CCA** and **ICA** functions. These have associated value cycle menu icons with the following values: proximal (Prx), middle (Mid), and distal (Dist). These functions enable measurement of the different sections of each vessel.

Diastolic/Systolic

The Measure menu for the Vascular Exam Type includes the **Diastolic/ Systolic** function that enables measurement of different phases of the cardiac cycle.

E/A

The Measure menu for the Fetal Echo Exam Type includes the **E/A** function, that enables measurement of the passive filling of the left ventricle (E) and the atrial kick (A).

Calipers

The z.one provides several types of calipers. The user can place a single caliper on a live image, and multiple calipers on a frozen image, from an open or archived exam. The caliper associated with the first item in the exam-specific Measurement menu is automatically activated when the Measure menu is displayed.

Calipers display in green when they are active, and in white when set. Images can be saved with calipers in place. The Data Display Box shows dynamic measurements and calculations data for the active caliper(s).

Data Display Box (DDB)

The DDB (Data Display Box) displays at the bottom right of the screen. The DDB is visible in all imaging modes when the user is performing a measurement, whether the image is live or frozen.

During live imaging in B, M, or Color modes, the DDB displays the depth from the transducer face to the position of the cursor. In PW mode, the caliper shows the velocity at the caliper position on the PW strip.

On frozen images, the DDB displays data related to the measurements and calculations in progress.

When working with calculation packages, the data in the DDB are stored when the measurements have been completed (locked down). To complete measurements, press the Enter key (SuperCart), the Select key (Scan Engine), or Store / Print.

Generic Measurements Procedures

B-Mode

Depth

Depth measures the distance from the transducer face to the location of the caliper in the image. The Depth measurement result is displayed in the DDB and updated continuously as the user positions the caliper within the image.

To perform Depth measurements

1. Display a live or frozen B-mode image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. Use the trackball to position the caliper to the desired location within the image display. A Depth result displays in the DDB, and updates as the user positions the caliper within the image.

4. Press the **Measure** button to remove the single caliper and exit Generic Measurements.

Distance

Distance measurements displays the span between the two B-mode calipers in the image. The **z.one** displays up to four Distance measurements on a single image simultaneously. The z.one displays the distance measurement result in the DDB and updates the measurement continuously as the user positions the active caliper within the image.

To perform Distance measurements

1. Freeze the display with a B-mode image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. 3.Use the trackball to position the caliper to the desired location within the image display. The DDB updates the depth result as the user positions the caliper within the image.
4. Press the **Set** button to fix the first Distance caliper and activate the second Distance caliper.
5. Use the trackball to position the caliper to the desired location. The DDB updates the distance result as the user positions the caliper within the image.

   NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second Distance calipers; allowing positional corrections to be made to both caliper instances.

6. To activate additional distance measurements, press the **Measure** button (SuperCart) again or press the **Select** button twice (Scan Engine).

   NOTE: Pressing the **Measure** button while a completable Distance measurement is being displayed, completes the measurement and starts another (up to the maximum of four) Distance measurement.

7. Unfreeze the image to exit measurements and return to live imaging.

Circ/Area (Ellipse)

The Circ/Area measures the circumference and area delineated by an ellipse drawn in the image. The DDB displays the ellipse circumference and area

results and continuously updates the results as the Ellipse shape (as defined by the caliper positions and outline) is changed within the image.

NOTE: Ellipse must be selected for the Area Method (**Tools Tab** | **System Setup** | **Calcs** | **General** and select Ellipse button under Area Method)

To perform Ellipse circumference/area measurements

1. Freeze the display with a B-mode image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.
3. Use the Menu Control navigation to highlight the Circ/Area.

   NOTE: A Measure menu is auto-selected when it is highlighted.
4. Use the trackball to position the caliper to the desired location within the image display. The DDB displays the Depth and updates the result as the user positions the caliper within the image.
5. Press the Set button to fix the first caliper and activate the second caliper, displaying a circle connecting the two calipers.
6. Use the trackball to position the caliper to the desired location within the image display. The DDB displays the circumference and area of the circle and the z.one update the results as the user positions the caliper within the image.
7. Press the Set button to fix the second caliper and select the Ellipse outline.
8. Use the trackball to change the eccentricity of the outline within the fixed caliper positions.

   NOTE: Pressing the **Set** button again toggles the active selection between the first caliper, second caliper, and the outline; allowing corrections to be made to both the size and shape of the Ellipse.
9. Press the **Measure** button to remove the Ellipse tools and exit Generic Measurements.

Circ/Area (Trace)

The Circ/Area measures the circumference and area delineated by a Trace outline drawn in the image. The **z.one** can simultaneously display up to two Traces on a single image. The **z.one** displays the Trace circumference and area results in the DDB when the Trace outline is closed.

NOTE: Trace must be selected for the Area Method (**Tools Tab** | **System Setup** | **Calcs** | **General** and select **Trace** button under Area Method).

To perform Trace circumference/area measurements

1. Freeze the display with a B-mode image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when Generic Measurements is activated.

3. Use the Menu Control navigation to highlight the Circ/Area.

   NOTE: A Measure menu is auto-selected when it is highlighted.

4. Use the trackball to position the caliper to the desired location within the image display. The **z.one** displays (in the DDB) the Depth result and the **z.one** updates the result as the user positions the caliper within the image.
5. Press the **Set** button to fix the first Trace caliper and activates the second Trace caliper.
6. 6.Draw the Trace outline using the trackball; as the trackball is moved, a trail of small dots are left behind to create the outline of the desired area.
7. Press the **Set** button to fix the second Trace caliper and complete the Trace outline.

   NOTE: Any gap in the outline between the first and second Trace calipers will be automatically closed by a straight connecting line when the second Trace caliper position is fixed.

8. 8.Press the Delete (Calc) button (SuperCart) or the Back button (Scan Engine) to undo any portions of the trace (each press of the delete or back button removes the last small dot.
9. To activate additional Trace circumference/area measurements (up to a maximum of two), press the **Select** button to invoke another Trace measurement instance.
10. Press the **Measure** button to remove the Trace tools and exit Generic Measurements.

M-Mode

Depth

The Depth measures the vertical distance from the top of the strip (transducer face) to the position of the cursor / caliper in the M-mode Strip. The DDB displays the Depth measurement result and continuously updates the result as the user positions the cursor / caliper within the image.

To perform Depth measurements

1. Acquire a live or frozen M-mode Strip image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when Generic Measurements is activated.

3. Use the trackball to position the cursor (vertical line) and caliper (horizontal line on cursor) to the desired location within the M-mode Strip display. The DDB displays the Depth result as the user positions the cursor/caliper within the strip image.
4. Unfreeze the image to clear the M-mode depth caliper and return to live imaging.

Distance

The Distance measures the vertical distance between two calipers on a single cursor line in the M-mode Strip. The **z.one** can simultaneously display up to four Distance measurements on an M-mode Strip image. The DDB displays the Distance measurement result and the **z.one** continuously updates the result as the user positions the cursor / caliper within the M-mode Strip image.

To perform Distance measurements

1. Freeze the display with an M-mode Strip image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when Generic Measurements is activated.

3. Use the trackball to position the cursor (vertical line) and caliper (horizontal line on cursor) to the desired location within the M-mode Strip display. The DDB updates the depth result as the user positions the cursor/caliper within the image.

4. Press the **Set** button to fix the first Distance cursor/caliper and activate the second Distance caliper.

   NOTE: The first Distance cursor/caliper is fixed at its current position in the M-mode Strip when the user presses the **Set** button, and a second caliper (horizontal line) is activated on the fixed cursor.

5. Use the trackball to position the caliper to the desired location along the fixed cursor. The DDB updates the Distance result as the user positions the caliper within the image.

   NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second Distance calipers, allowing positional corrections to be made to both caliper instances along the fixed cursor.

6. To activate additional distance measurements (up to a maximum of four), press the **Select** button twice (once to complete the current measurement instance and a second time to invoke another Distance measurement instance).

7. Unfreeze the image to exit measurements and return to live imaging.

PW Doppler Mode

Velocity

Velocity is measured (relative to the selected Scale and Baseline position) at the caliper's position in the PW Doppler Strip. The **z.one** can simultaneously display up to four Distance measurements on a PW Doppler Strip image. The **z.one** displays the velocity measurement result in the DDB and continuously updates the result as the user positions the caliper within the PW Doppler Strip image.

To perform Velocity measurements

1. Acquire a live or frozen PW Doppler Strip image.

2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when Generic Measurements is activated.

3. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The DDB updates the velocity result, as the user positions the caliper within the strip image.

4. To activate additional Velocity measurements (up to a maximum of four), press the **Select** button twice (once to complete the current measurement instance and a second time to invoke another Velocity measurement instance).

5. Unfreeze the image to exit measurements and return to live imaging.

Resistivity Index

The Resistive Index (RI) is defined as abs [(Max – Min) / Max], where Max and Min are determined by comparing the absolute velocities obtained by two concurrent PW Velocity calipers positioned within the context of the same PW Doppler Strip. Only a single instance of this tool can exist at any one time. The **z.one** displays (in the DDB) and continuously displays both Velocity results and their associated RI calculation result when the user positions either caliper within the PW Doppler Strip image.

NOTE: In the DDB, Max velocity is identified as PSV (Peak Systolic Velocity) and Min velocity is identified as EDV (End Diastolic Velocity).

To perform Resistive Index (RI) measurements

1. Freeze the display with a PW Doppler Strip image.

2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when Generic Measurements is activated.

3. Use the Menu Control navigation to highlight the RI selection.

4. The PSV caliper will be displayed when the user presses the **Select** button.

5. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. At this time, the DDB only displays the PSV velocity result and updates the result as the user positions the caliper is positioned.

6. Press the **Set** button to fix the PSV velocity caliper and displays the EDV velocity caliper.

   NOTE: The RI result is calculated and displayed once both velocity calipers have been activated.

7. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The DDB only displays the EDV velocity result and updates the RI calculation result as the user positions the caliper within the strip image.

   NOTE: If the absolute value of the EDV velocity result is greater than the current PSV result, the EDV and PSV result displays are swapped and the caliper becomes a PSV caliper. The converse is also true, when the absolute value of the PSV velocity result is less than the current EDV result.

   NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second velocity calipers, allowing positional corrections to be made to both caliper instances within the strip image.

8. 8.Press the Delete (Calc) button (SuperCart) or the Back button (Scan Engine) to successively erase trace "dots".

9. Unfreeze the image to exit measurements and return to live imaging.

Pulsatility Index

The Pulsatility Index (PI) is defined as (Max – Min)/TA max, where Max and Min are determined by comparing the absolute velocities obtained by two concurrent PW Velocity calipers positioned within the context of the same PW Doppler Strip. TA max is generated by tracing the peak outline of one complete Doppler spectrum, which determines the average (mean) of the maximum velocities. Only a single PI measurement can be performed at any given time. The **z.one** displays both Velocity results and their associated RI calculation result in the DDB and continuously updates them after completing the PW trace when the user positions either caliper within the PW Doppler Strip image.

NOTE: In the DDB, Max velocity is identified as PSV (Peak Systolic Velocity) and Min velocity is identified as MDV (Minimum Diastolic Velocity).

To perform Pulsatility Index (PI) measurements

1. Freeze the display with a PW Doppler Strip image.

2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. Use the Menu Control navigation to position selection highlight on PI.
4. The first PW trace caliper will be displayed when the user presses the **Select** button.
5. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. There is no DDB display at this time.
6. Press the **Set** button to fix PW trace start point and activate the second velocity caliper.
7. Use the trackball to trace the desired portion of the waveform within the PW Doppler Strip display. There is no DDB display at this time.
8. Press the **Delete (Calc)** button (SuperCart) or the **Back** button (Scan Engine) to undo any portions of the trace.
9. Press the **Set** button to fix the trace end point and complete the PW trace and activate the PSV velocity caliper. At this time, the DDB only displays the TA max and the PSV velocity results. The **z.one** continuously updates the PSV velocity result as the user positions the caliper within the strip image.

   NOTE: When the trace is completed, a vertical line is dropped from the start and end points of the trace to the baseline to clearly delineate the traced region used for TA max.

   NOTE: The PSV velocity caliper is automatically positioned at the maximum traced velocity.

10. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The **z.one** only updates the PSV velocity result as the user positions the caliper within the strip image.

    NOTE: If the absolute value of the MDV velocity result is greater than the current PSV result, the MDV and PSV result displays are swapped and the caliper becomes a PSV caliper. The converse is also true, when the absolute value of the PSV velocity result is less than the current MDV result.

    NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second velocity calipers, allowing positional corrections to be made to both caliper instances within the strip image.

11. Press the **Set** button to fix the PSV velocity caliper and activate the MDV velocity caliper.

    NOTE: If the absolute value of the MDV velocity result is greater than the current PSV result, the MDV and PSV result displays are swapped and the caliper becomes a PSV caliper. The converse is also true, when the absolute value of the PSV velocity result is less than the current MDV result.

NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second velocity calipers, allowing positional corrections to be made to both caliper instances within the strip image.

12. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The **z.one** continuously updates the PSV and MDV velocity results and the PI calculation result as the user positions the calipers within the strip image.

13. Unfreeze the image to exit measurements and return to live imaging.

Acceleration

The Acceleration (Accel) is defined as DV/DT, where DV is the velocity difference and DT is the time interval between two points as delineated by two concurrent PW Velocity calipers positioned within the context of the same PW Doppler Strip. Only a single instance of this tool can exist at any one time. The DDB displays both the Delta Velocity and Delta Time results and their associated Accel calculation result, and continuously updates them when the user positions either caliper within the PW Doppler Strip image.

To perform Acceleration (Accel) measurements

1. Freeze the display with a PW Doppler Strip image.

2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. Use the Menu Control navigation to position selection highlight on Accel.

4. The first velocity caliper will be displayed when the user presses the **Select** button.

5. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. At this time, the DDB only displays the velocity result and the **z.one** continuously updates the result as the user positions the caliper within the strip image.

6. Press the **Set** button to fix the first velocity caliper and activate the second velocity caliper.

   NOTE: The delta velocity, delta time, and acceleration results are calculated and displayed once both velocity calipers have been activated.

7. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The DDB continuously updates the Time, Velocity, and Accel results as the user positions the caliper within the strip image.

   NOTE: Acceleration is always calculated in the direction of positive time, The velocity caliper positioned at the earliest strip time is always the startpoint (and the other caliper is the endpoint) for calculating the delta velocity, delta time, and acceleration results.

   NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second velocity calipers, allowing positional corrections to be made to both caliper instances within the strip image.

8. Unfreeze the image to exit measurements and return to live imaging.

Systolic/Diastolic Ratio

The PW Systolic/Diastolic (S/D) Ratio is defined as abs [(Max/Min], where Max and Min are determined by comparing the absolute velocities obtained by two concurrent PW Velocity calipers positioned within the context of the same PW Doppler Strip. Only a single instance of this tool can exist at any one time. The DDB displays both Velocity results and their associated SD calculation result and continuously updates the results when the user positions either caliper within the PW Doppler Strip image.

NOTE: In the DDB, Max velocity is identified as PSV (Peak Systolic Velocity) and Min velocity is identified as EDV (End Diastolic Velocity).

To perform Systolic/Diastolic (S/D) Ratio measurements

1. Freeze the display with a PW Doppler Strip image.
2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. Use the Menu Control navigation to position selection highlight on S/D.
4. The PSV velocity caliper will be displayed when the user presses the **Select** button.

5. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. At this time, the **z.one** only displays (in the DDB) the PSV velocity result and the **z.one** updates the result as the user positions the caliper within the strip image.

6. Press the **Set** button to fix the PSV velocity caliper and activate the EDV velocity caliper.

   NOTE: The S/D result is calculated and displayed once both velocity calipers have been activated.

7. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. The **z.one** only updates the EDV velocity result and the S/D calculation result as the user positions the caliper within the strip image.

   NOTE: If the absolute value of the EDV velocity result is greater than the current PSV result, the EDV and PSV result displays are swapped and the caliper becomes a PSV caliper. The converse is also true, when the absolute value of the PSV velocity result is less than the current EDV result.

   NOTE: Pressing the **Set** button again toggles the active caliper selection between the first and second velocity calipers, allowing positional corrections to be made to both caliper instances within the strip image.

8. Unfreeze the image to exit measurements and return to live imaging.

A/B Ratio

The A/B Ratio is defined as V1/V2, where V1 and V2 velocities obtained by two PW Velocity caliper measurements separated by an Unfreeze/Freeze cycle. Only a single instance of this tool can exist at any one time. The DDB displays each Velocity result and continuously updates the result when the user positions its caliper within the PW Doppler Strip image. The DDB does not display all results together until the V2 velocity measurement has been activated and/or completed.

To perform A/B Ratio measurements

1. Freeze the display with a PW Doppler Strip image.

2. Press the **Measure** button.

   NOTE: The first item in the Measure menu is auto-selected when the user selects **Measure**.

3. Use the Menu Control navigation to position selection highlight on A/B.

4. The Vel1 velocity caliper will be displayed when the user presses the **Select** button.

5. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. At this time, the **z.one** only displays (in the DDB) the Vel1 velocity result and updates the result as the user positions the caliper within the strip image.

6. Press the **Select** button to fix the caliper and complete the Vel1 velocity measurement (activates the Vel2 velocity caliper). At this time, the DDB displays the Vel1, Vel2 velocity results and the A/B calculation result. The **z.one** continuously updates the Vel2 velocity result as the user positions the caliper within the strip image.

7. Unfreeze the PW Doppler Strip and acquire new data, and then press Freeze.

8. Press the **Measure** button.

   NOTE: The A/B Ratio Measure menu is auto-selected and the Vel2 caliper is displayed when the user selects **Measure**.

9. Use the trackball to position the caliper to the desired location within the PW Doppler Strip display. At this time, the DDB displays the Vel1, Vel2 velocity results and the A/B calculation result. The **z.one** continuously updates the Vel2 velocity result as the user positions the caliper within the strip image.

10. Press the **Select** button to fix the caliper and complete the Vel2 velocity measurement. This also ends the A/B measurement.

11. Unfreeze the image to exit measurements and return to live imaging.

OB Calculation Package

The OB Exam Type includes an extensive selection of supported measurements and their associated calculations. The actual measurement availability is determined by the OB Setup configuration as well as the Preset selection and the active imaging mode when the OB Calculation Package is invoked.

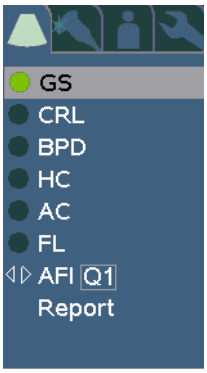


Figure 5-4. **Calculations Menu**

The OB Calculations Package also supports the addition of new measurements based on user-supplied table data (select **Tools Tab | System Setup | Calcs | Custom** to access this feature).

The following OB calculations (OB calcs) are available for all Presets except Fetal Echo.

B-mode	PW Doppler	M-mode
BPD	UT S/D	HR
GS	Cord S/D	
CRL	Umb A S/D	
BPD	Plac	
OFD	Ut A	
HC	Fetal Aorta	
AC	MCA	
TTD	HR	

B-mode	PW Doppler	M-mode
FL		
HL		

NOTE: Measurements from the Generic Measurement Package are also available when the OB Exam Type is selected, and can be accessed by pressing the **Measure** button. Pressing the **Measure** button exits the OB Calculations Package if it was active.

The following OB calculations are available for the Fetal Heart Preset.

B-mode	PW Doppler	M-mode
Asc Aorta	MV peak E/A	RV Wall Sys
MPA	TV peak E/A	RV Diam Sys
Duct Art	Asc Aorta	IVS Sys
ivs s	Desc Aorta	LV Diam Sys
RA	MR	LVPW Sys
RV Wall	TR	OB Calcs
RVID S/D	MPA	
LVID S/D	Duct Art	
LVPW S/D	IVC	
Heart Circ	Duct Ven	
Thor Circ	OB Calcs	
OB Calcs		

OB Worksheets and Reports

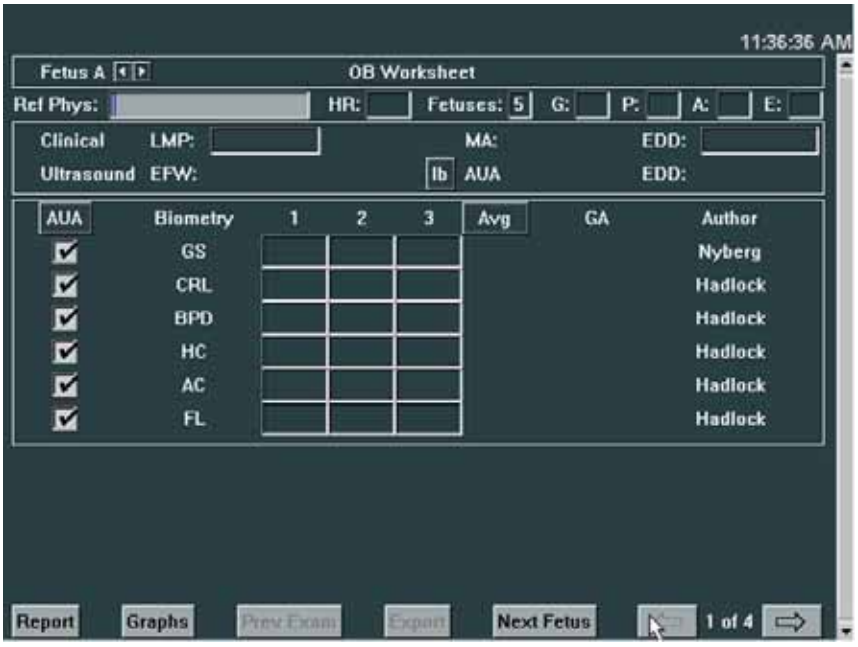


Figure 5-5. **OB Worksheet (page 1)**

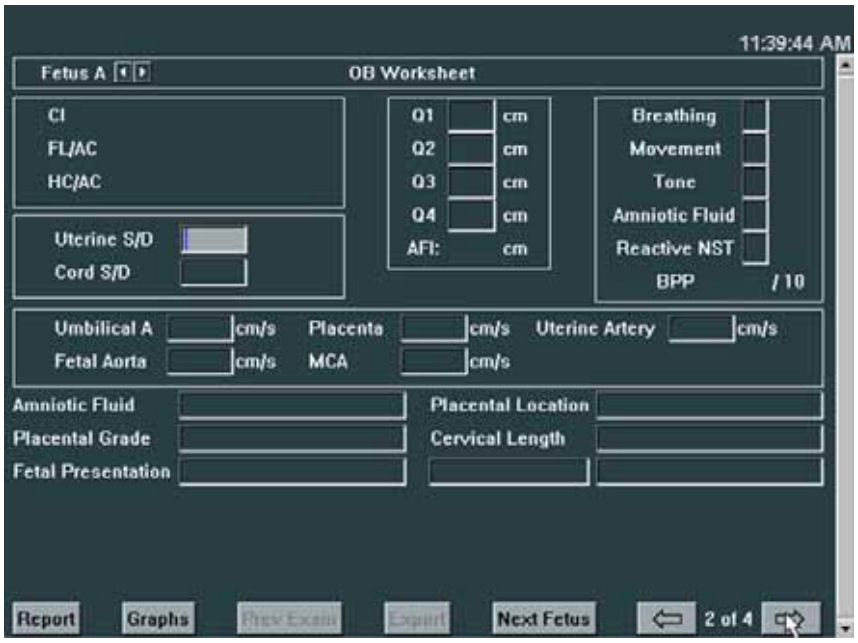


Figure 5-6. **OB Worksheet (page 2)**

Figure 5-7. **OB Worksheet (page 3)**

Figure 5-8. **OB Worksheet (page 4)**

Figure 5-9. **OB Report**

Procedures for OB Calculation Packages

To acquire GS calculation

1. Optimize the B-mode image of the GS.
2. Press **Freeze** to open the Freeze menu and freeze the B-mode image.
3. To view the Calculations menu, press **Calc** (SuperCart or *mini*Cart) or select Calc (Scan Engine).
4. The Obstetrics Calculations menu displays in the Control area. GS (gestational sac) is active by default. An active caliper displays in the Image area.
5. Use the trackball to position the active caliper to the desired location within the image display.
6. Press the Set button to fix the first Distance caliper and activate the second caliper.
7. Press **Enter** (SuperCart or *mini*Cart) or **Select** (Scan Engine). This will finalize the measurement for the first pair and bring up the first distance caliper of the second pair.
8. Use the trackball to position the first distance caliper of the second pair to the desired location within the image display.

9. Press the **Set** button to fix the first Distance caliper of the second pair. This will activate the second distance caliper of the second pair.
10. Use the trackball to position this caliper and then press **Enter** (SuperCart or *mini*Cart) or **Select** (Scan Engine). This will finalize the measurement for the second pair and bring up the first distance caliper of the third pair.
11. Press **Freeze** to unfreeze the current image and obtain your next image. (Note that the caliper will momentarily disappear)
12. Freeze on the new image and press **Calc** (SuperCart or *mini*Cart) or select Calc (Scan Engine).
13. This will re-activate the first distance caliper of the third pair.
14. Use the trackball to position the first distance caliper of the third pair to the desired location within the image display.
15. Press the **Set** button to lock the first Distance caliper of the third pair. This will activate the second distance caliper of the third pair.
16. Use the trackball to position the second distance caliper of the third pair to the desired location within the image display.
17. Press **Enter** (SuperCart or *mini*Cart) or Select (Scan Engine) to lock the third caliper pair. All three distance measurements are copied to the Worksheet. The data display in the Measurements window inverts (to black-on-white).
18. To view the Obstetrics Worksheet:
19. Press **Report**.(SuperCart or *mini*Cart) or from the Calculations menu, select Worksheet (Scan Engine)
20. To edit the Worksheet, highlight the value to be edited, then press **Del Txt** or overtype replacement text.
21. To review the Report, press **Select** to toggle between the Worksheet and the Report.

To perform a heart-rate (HR) calculation

1. Optimize the B-mode image.
2. Press M, use the trackball to position the green vertical bar in the active M-mode image.
3. Freeze the image.

4. To open the Calculations menu.
5. Press **Calc** button on the SuperCart, Scan Engine (or *mini*Cart Touchscreen)
6. Heart Rate is active by default. A green vertical bar displays on the scroll.
7. Use the trackball to position the green vertical bar at the beginning of a cardiac deflection. Press Set to lock the position of the bar. A second bar becomes active.
8. Use the trackball to position the second vertical bar at the beginning of the next cardiac deflection (the number of cycles is set on the config panel).
9. Press Enter (SuperCart or *mini*Cart Touchscreen) or Select (Scan Engine) to lock the position of the second bar. The data is stored to the Worksheet, and the data display in the Measurements window inverts (black on white).

Additional Calculation Packages

Examples of the other supported calculation packages are described in the tables that follow. Steps for performing these calculations are similar to those previously described in the Generic and OB Calculation Package examples. Due to this similarity, detailed steps will not be repeated for these additional calculation packages.

Gyn and Follicular Package

B-mode	PW Doppler
Uterine Volume	Rt/Lt Ov Ri
Endometrial Thickness	Ut RI
Rt/Lt Ovary Volume	
Rt/Lt Follicle* (x 10)	
Follicle Preset only	

Vascular Packages

Carotid Calc Package

B-mode	PW Doppler
Right/Left	Right/Left
CCA Sten [Prx Mid Dist]	CCA [Prx Mid Dist]
ICA Sten [Prx Mid Dist]	ICA [Prx Mid Dist]
ECA Sten	ECA
Vert Sten	Vertebral
Subclavian Sten	Subclavian

Upper Extremity Arterial Calc Package

B-mode	PW Doppler
Right/Left	Right/Left
Subclavian Sten	Subclavian
Axillary Sten	Axillary
Brachial Sten	Brachial
Radial Sten	Radial
Ulnar Sten	Ulnar

Lower Extremity Arterial Calc Package

B-mode	PW Doppler
Right/Left	Right/Left
CIA Sten	CIA
EIA Sten	EIA
CFA Sten	CFA
SFA Sten [Prx Mid Dist]	SFA [Prx Mid Dist]
Pop Sten	Pop
ATA Sten	ATA
Peroneal Sten	Peroneal
PTA Sten	PTA
Dors Ped Sten	Dors Ped

Lower Extremity Venous Calc Package

Deep	Superficial
IVC	SFJ
CIV	Thigh [Prx Mid Dist]
EIV	Knee
CFV	Calf [Prx Mid Dist]
SFV [Prx Mid Dist]	SPJ
Profunda	LSV [Prx Mid Dist]
Pop	
PTV	
Peroneal	
ATV	

Upper Extremity Venous Calc Package

Deep	Superficial
IJV	CAJ
Innom	Upper Ceph [Prx Mid Dist]
Subclav	LAV
Axillary	Forearm Ceph [Prx Mid Dist]
Brachial [Prx Mid Dist]	BAJ
Radial	Upper Bas [Prx Mid Dist]
Ulnar	MAV
Volar	Forearm Bas [Prx Mid Dist]
	Digital

Worksheet and Report Pages

Each section of the Worksheet has a corresponding section in the Report if there is no data in it. During the exam, the user can access Report pages directly from the Worksheet pages, and vice versa, using the Report and Worksheet buttons, respectively.

The **z.one** stores the Patient record data from the Patient Information form into the Worksheet and Report. The user can also edit or update the Patient Information form from the Worksheet if the information was incorrectly entered or not entered at the beginning of the examination.

The **z.one** enters Measurement data into the Worksheet automatically from the DDB when the measurement is complete. The user can edit this data directly in the Worksheet. When the user completes all data fields required for a calculation, the **z.one** calculates and displays the derived value. The **z.one** updates this derived value when any related data field is edited.

The user performs all data deletion and editing in the Worksheet. Certain data from the Worksheet (e.g., derived values) are displayed in the Report. No data fields in the Report are directly editable. When the user edits the Worksheet, the changes are reflected immediately in the Report.

When the exam is ended, the **z.one** saves the data to the exam directory, and all the data in the current exam is cleared. If the exam is restarted via the Restart key, all the Calc data will be restored for that exam. The Calc data can then be changed and added to, for that exam in exactly the same way as if the exam had not been interrupted.

Types of data fields

The Worksheet has five types of data fields:

Free text data field

The free text data field accepts alphanumeric characters entered via the keyboard or the soft keyboard. Each such field has a maximum character count specific to each field. Text wraps until the maximum character count is reached.

Numeric data field

The numeric data field accepts only numeric characters and the decimal point entered via the DDB, the keyboard, or the VKB. Any other entry is ignored. In addition, superfluous precision after the decimal place are not allowed.

Date data field

The Date data field accepts only a date in the format selected in system setup.

Highly restricted data field

This highly restricted data field accepts only certain characters; for example, the BPP data field accepts only 0 (zero) or 2. All other characters are ignored.

Checkbox

This checkbox toggles between two states: activated (checked) and deactivated (unchecked). To activate or deactivate a checkbox, highlight the field by moving the cursor into it with the trackball, and then press Set. (Or use the tab key to traverse to the checkbox and press the enter key - the "return arrow" key

z.one Measurement Accuracy

The description of the fundamental accuracy of 2D, time and velocity measurements with **z.one** ultrasound systems applies to all transducer types.

2D Measurement Accuracy

Since distance is a measure of the relative separation between two pixels in the image, distance is not affected by the delay tolerances in the front-end echo acquisition system, including variations in the response times of the transducer and analog electronics.

The two main sources of error that may affect distance measurements in the **z.one** system are:

- Sound speed assumed by the system does not match the actual sound speed of the medium
- Algorithmic error associated with floating point versus fixed point math

In the **z.one**, the conversion of time delay to distance is based on a sound speed of 1540 m/s for all probes and application types. This is independent of the Speed of Sound Correction (discussed in the "Optimize Feature" on page 3-14) which, if activated, affects only the focus quality (and not the scaling) of the image. Due to sound speed variations between different types of tissue, caliper measurement errors in the order of 5% are expected for images of the human body.

With respect to algorithmic error, the entire digital signal processing chain in the **z.one** system is designed with sufficient precision to ensure that the cumulative digital processor rounding errors from detection to scan

conversion will not exceed one pixel in the final XY display. While the display 2D image size varies with the image depth setting and zoom state, the image generally takes up more than 100 pixels along the range dimension; hence, one pixel corresponds to a distance error of less than 1% of the maximum range of the image.

Based on the above considerations, it should be safe to assume that for a medium whose sound speed is close to the 1540 m/s, the caliper distance measurement fractional error is:

- Tolerance in distance < +/-2% plus (1% of maxRange/distance)

The area and circumference accuracies can be derived from the distance accuracy as follows:

- Tolerance in area =
  ((1+lateral distance tolerance) * (1+axial distance tolerance) -1)
  < +/-4% plus (2% of maxRange/smaller of 2 dimensions)

- Tolerance in circumference =
  sqrt(2)*(maximum of 2 distance errors) *100
  < +/-3% plus (1.4% of maxRange/smaller of 2 dimensions)

The above accuracy statements are consistent with 2D measurement tests performed using a tissue mimicking phantom with 0.5 dB/cm-MHz attenuation and a sound speed of 1540 m/s.

Elapsed Time or Rate Measurement Accuracy

In M-mode and PW Doppler, strip records of tissue motion or blood velocities over time are produced. The user may use the calipers to analyze these records to measure the elapsed time between events, or, conversely, to determine the frequency of such events (as in heart rate determinations). The fundamental accuracy of these measurements depends on the accuracy of the caliper placement in measuring elapsed time on the time record.

Since the smallest possible error in placing each caliper is ±1 pixel, the average minimum error in estimating the elapsed time between two events is approximately ±1.5 pixels. The error in estimating the elapsed time between two events occurring 1.0 second apart depends upon the sweep speed. The **z.one** display strip is approximately 490 pixels wide, and the corresponding error estimates are summarized in the following table.

Table 5-1. **Accuracy of Caliper Measurements of Elapsed Time or Rate for the z.one**

Sweep Speed (pixels/sec)	Display Width (sec)	Error in Measurement (1.0 sec)
180	2.7	0.8%
90	5.4	1.7%
60	8.1	2.5%

These accuracy statements are consistent with PW elapsed time measurement tests, performed using a string phantom with distilled water as the fluid medium.

Color Doppler Registration Accuracy

For CD scanning of flow phantoms, with a sound speed of 1540 cm/sec, the registration error between CD and 2D mode is generally less than 1.0mm.

PW Doppler Velocity Measurement Accuracy

While CD gives an indication (at many points simultaneously) of the presence or absence of flow and its dynamic behavior during the cardiovascular cycle, PW Doppler provides a more precise quantification of flow velocity within the PW sample volume.

Velocity Accuracy in PW Doppler

Flow phantom measurements in PW mode demonstrate that velocity estimates can be achieved within ±10% of the calculated velocity in a small sample gate placed at the center of the 5mm inner diameter flow tube, for volume flow rates from 0.15 to 1.0 meters/sec and with Doppler angle of 50°.

Angle Estimation

The precision of angle estimation is ±0.5° with **z.one** systems. As with most electronically steered systems, however, the major error in angle estimation occurs through operator error in adjusting the angle calipers. Therefore, the operator should exercise care in the use of the angle calipers to achieve accuracy in their placement.

Numeric Display Accuracy

For display on the z.one monitor, all measurements and calculation results are generally rounded to a maximum of 2 digits after the decimal place. This policy ensures consistency between measured quantities (e.g. distance) and calculated values (e.g. area).

6

Archive and Review

Any screen displayed in the Image area can be saved (stored) electronically to the internal CompactFlash in the Scan Engine. Ultrasound images and data screens, are stored as screen images (.DCM files). In addition to still images, the **z.one** can be used for capturing dynamic clips of realtime image frame sequences.

The number of still images (or number of clips) that can be stored for an exam is limited only by the capacity of the internal CompactFlash memory. The duration of the stored Clip is configurable by the user in the **Storage Media** screen. It is recommended that images or clips that have been printed, or stored to a DICOM storage device (from the internal CompactFlash), be deleted on a regular basis. This will ensure adequate space is available for actively storing new images, as well as optimize the performance (speed) for image storage on the **z.one**.

In-progress exam images, and images from exams stored on the internal CompactFlash can be recalled for review.

Annotations and measurements performed on in-progress exams can be saved as part of the archived images. Exams performed during the current calendar day can be restarted, and images in those exams can have additional annotations and measurements performed upon them.

Images in exams that were originally performed prior to the current calendar day ***cannot*** be restarted; however they can be opened for review (read only). Measurements can be performed on these images, however those measurements cannot be saved.

In addition to local storage on the internal CompactFlash storage, the user can simultaneously save still images, screens, and clips to DICOM network storage devices. The networking and DICOM parameters must be pre-configured into the **z.one**, prior to storing or printing to external devices.

Refer to "Configuring DICOM" on page 8-1. Image files cannot be retrieved from network storage for review on the **z.one**. These files can, however, be sent to a network review station directly from the **z.one**.

Tools for Archive and Review

"Media" Configuration - Compression Settings:

The size of the stored image files is determined by the pre-configured "***Compression Level***" and "***Compression Quality***" settings, on the "*Removable Storage* ***Media***" configuration screen.

Compressing images allows for smaller image file sizes, which reduces disk storage and improves transfer rates (if DICOM network / printer transfers of archived images are later performed).

The ***RLE Lossless*** compression method uses a coding format that reduces image file size, without any loss of raw data during transmission.

The ***JPEG Lossy*** method provides a significant reduction in file size (i.e. more compression than RLE Lossless or None), with some level of loss of raw data during the transfer. When ***JPEG Lossy*** compression type is selected, the user can specify the level of compression (and resultant loss), using the Compression Level (85-100%) menu entry.

1. To access the "*Removable Storage* ***Media***" configuration screen, select **Tools | System Setup | Archive | Media**

2. Using the drop-down box in the **Compression Level** option, select the desired level of compression that will be used for ***Still Image Storage*** under that main heading.

3. Repeat this process for configuring the desired **Compression Level** that will be used for ***Clip Image Storage***, under that menu heading.

NOTE: If ***JPEG Lossy*** compression format is selected (for either storage method), using the cursor on the on-screen bar graph select the desired percentage (from 85% - 100%) of compression *Quality* that is desired. (higher % equals larger file sizes, but with less loss of source resolution)

"Media" Configuration - (Clip Store) Duration Setting:

The duration of time that will be captured during each Clip Image Loop Store operation, is dependent upon the time interval (0:03 to 2:00) previously configured by the User. The loop store ***duration*** parameter is configured in the "*Removable Storage* ***Media"*** configuration screen.

1. To access the "*Removable Storage **Media***" configuration screen, select **Tools | System Setup | Archive | Media**

2. Under the ***Clip Storage*** main heading, utilize the drop-down box next to the **Duration** heading, to select the desired interval of time that will be applied during subsequent Clip Store operations.

NOTE: The time intervals available for configuration (using the drop-down box) range between 3 seconds (0:03) and 2 minutes (2:00)

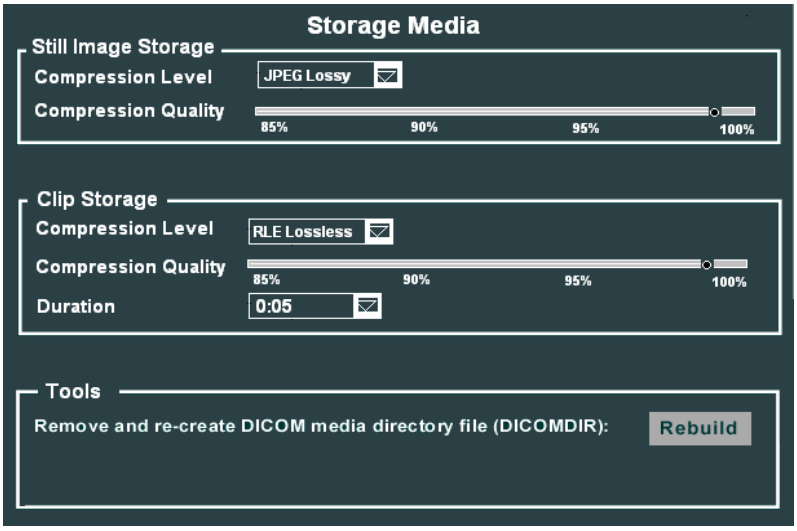


Figure 6-1. **Storage Media Configuration Menu**

"Storage Media": Tools - Maintenance:

The **Tools** area of the Storage Media page provides the ability for the User to perform a soft-maintenance ("rebuild") operation on the image storage directory file (DICOMDIR). This maintenance operation is intended to be performed **only** in the rare event that the User may experience problems with the storage or retrieval of archived exams.

The TOOLS area allows for performing the following operation:

- Rebuilding (removal and re-creation) the DICOMDIR image archive directory file on the media; utilizing currently archived exam data.

Store/Print Keys: Paper Printing (B/W or Color) to Sony Printers

In addition to initiating image storage to the internal CompactFlash storage, the removable USB Memory Stick, and the DICOM storage device (where

applicable) the **Store** and **Print** keys can be configured to trigger a print to a locally attached paper printer.

There are two categories of paper printers potentially used locally on the **z.one.**; analog video capture, or a digital USB transfer type.

NOTE: In order to generate the trigger signal to the video printer device (when the **Print** or **Store** keys are pressed) live imaging must be stopped, by having previously pressed the **FREEZE** key.

On the SuperCart, the devices currently supported for analog video printing include:

- Sony UP-897MD (Black / White)
- Sony UP-21MD (Color)

On the *mini*Cart, the digital USB print device currently supported is:

- Sony UP-D897 Digital USB 2.0 (Black / White)

1. To access the "***Print/Store Buttons***" configuration screen, select **Tools | System Setup | Archive | Print/Store**

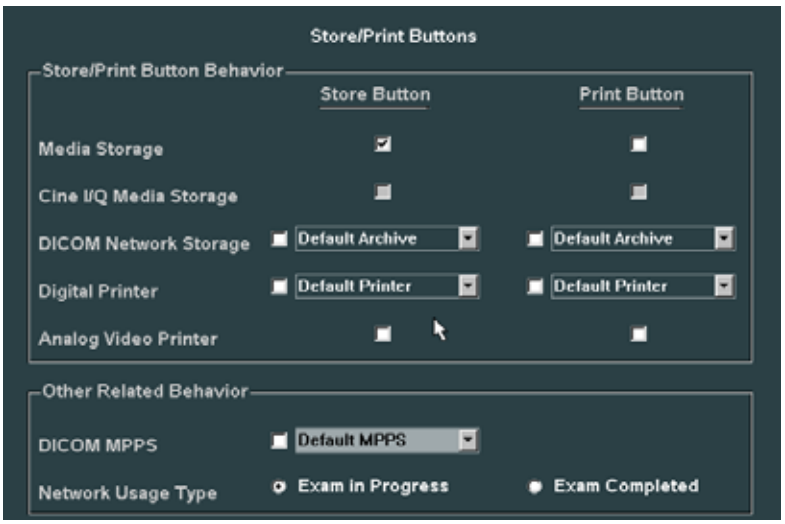


Figure 6-2. **DICOM Print/Store Button Configuration Menu**

DICOM (Network) Image Transfer Configuration:

If enabled, images are immediately stored to the internal CompactFlash storage (each time the **Store** key is pressed). However the timing for when the images are placed into the DICOM Queue, and sent over the network to the DICOM storage device, is user configurable.

This function is configured using the "**Network Usage Type**" selection, in the **Archive** -> **Print/Store** menu.

Options:

1. **"Exam in Progress"**:

- Immediately places each successive image into the DICOM Queue (where network transfer will immediately begin) upon each press of the **Store** key by the user

2. **"Exam Completed"**:

- Images in exam are temporarily buffered, each time the user presses the **Store** key. Images are NOT placed into the DICOM Queue, and no network transfer is initiated to the DICOM storage device, until the user closes the current exam.

Store/Print Button Configuration:

1. To configure the **Store** or **Print** buttons, to be used for triggering local video **printing** of images, do the following:

   Point the cursor arrow over the white select box, to the left of the desired entry window, and press **Set** (to check the box). That will enable that function, for that button (Print or Store).

   Point the cursor over the arrow in the **Network Print** data field under the corresponding **Print** or **Store** button heading. Press **Set** to open the selection list of all configured printers. Printing options consist of remote printing (via a network connection) to a DICOM printer device, and / or printing to a locally attached video printer device (Sony UP-895MD or UP-21MD).

   On systems equipped with a paper printer option, printing to an attached Sony printer, is achieved by selecting either "**USB PRINTER**" or "**VIDEO PRINTER**" in the drop-down menu.

   Checking the box for the "**VIDEO PRINT**" selection, on the DICOM Print / Store Button screen, will enable the **Z.ONE** to send a remote trigger signal (via a cable connection) to one of the Sony video printer devices, each time the ***PRINT*** key on the SuperCart is depressed.

   For a *mini*Cart configuration, in the **Network Print** data field, selecting "**USB PRINTER**" will enable the **Z.ONE** to send a trigger command over the USB cable connection, to the Sony UP-D897 Digital USB Printer device, each time the ***PRINT*** key on the Scan Engine is depressed

   Highlight the preferred device, then press **Set**. The Nickname of the selected device displays in the data field.

   To save and exit, select **Apply** from the main menu to save the new configuration and return to the previous menu

Store/Print Keys: Still Image & Clip Image Stores

Figure 6-3. **Internal CompactFlash Icon Active and Inactive**

The **Store** and / or **Print** keys (SuperCart and Scan Engine) can be configured to be used to send the currently displayed image (Single Frame, in FREEZE mode), or a sequence of live imaging frames (Clip Image Store, in LIVE mode) to the internal CompactFlash.

The "***Store to Media***" selection must be made (for the desired key; **Print** or **Store**) in the **DICOM Print/Store Button** configuration menu. Refer to Figure 6-2, "DICOM Print / Store Button Configuration Menu," on page 6-4

In addition to initiating storage of images, the **Store** and **Print** keys can be configured to send images to the remote DICOM storage or print device, or trigger a video capture by a locally connected video printer device (Sony UP-895MD or Sony UP-21MD). See "Configuring DICOM" on page 8-1 for details on DICOM Store and Print configuration.

NOTE: For single frame image storage, prior to initiating the storage of an image (by pressing the **Store** or **Print** key), the user must first have frozen the image acquisition process by pressing the **Freeze** key.

To Store a Single Frame Image (SuperCart and Scan Engine)

1. Press the **Freeze** key to freeze the image.
2. Press the **Store** key to store the image.

The **z.one** beeps when an image store is initiated and displays a message that a store is in progress. This message disappears when the store operation is complete.

In departments that have activated and configured the DICOM module, the **Store** and **Print** keys may be configured to send to DICOM network storage devices and DICOM printers, in addition to storing images to the local internal CompactFlash.

To Store a Clip Image (SuperCart and Scan Engine)

1. Achieve desired scanning view of patient anatomy, and continue live scanning (do **not** press Freeze key).

2. Press the **Store** key to begin the capture (store) of the Clip Image sequence.

NOTE: The following events occur upon the START of a Clip Image Store sequence:

- **z.one** exhibits an audible "single-beep"
- A scrolling bar graph is displayed (in the lower right-hand corner of the display), illustrating the progress of the store sequence.
- The internal CompactFlash ICON (in the lower right-hand corner of the display) turns ***green***.

NOTE: The following events occur to indicate the END of a Clip Image Store sequence:

- **z.one** exhibits an audible "double-beep"
- The scrolling bar graph disappears for the screen
- The internal CompactFlash ICON (in the lower right-hand corner of the display) returns to normal color (*white*)

DICOM transfer of Clip Image Stores

In departments that have activated and configured the DICOM module, the **Store** and **Print** keys may be configured to send the Clip Image to DICOM network storage devices, in addition to storing the Clip Images to the local internal CompactFlash.

NOTE: In cases where the DICOM storage device (PACS system) at the installation site does **NOT** accept clip stores (still images only), the **z.one** should be configured for ***"Store still images only"***, in the DICOM Network Storage configuration menu. See Chapter 7 for detailed information on this configuration procedure.

To Open an Exam

Pressing the "New Patient" key (SuperCart or *mini*Cart) or selecting "New" from the Patient menu (Scan Engine) will bring up a screen that will allow the user to enter in specific patient information in creating a new exam.

In addition to this actively created new exam process, a new patient exam is automatically opened when the first image of a study is stored. If the user did not enter a patient ID on the Patient Information page (did not use the "New Patient" screen to enter patient information prior), the **z.one** automatically assigns the next available ID when the first image is stored.

Closing an Exam

An exam will be closed if any of the actions listed below are performed:

SuperCart & *mini*Cart:

- Pressing the **End Exam** key on the SuperCart or *mini*Cart keyboard.

SCAN ENGINE:

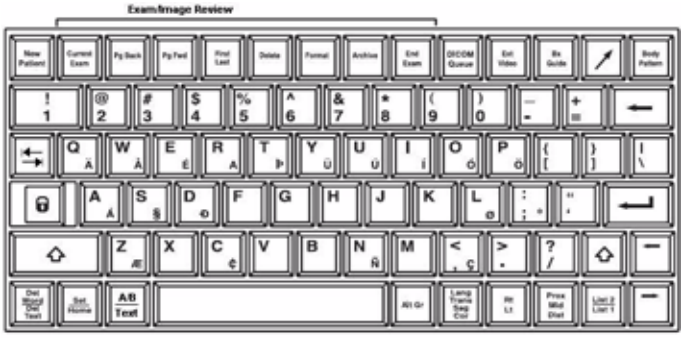
- Starting a new exam by selecting **New** on the Patient Information page.

Z.ONE OVERALL:

- Powering off the **z.one**.

Keyboard Keys (SuperCart & *mini*Cart)

SuperCart



***mini*Cart**

Figure 6-4. **SuperCart & *mini*Cart Keyboard Keys**

The SuperCart and *mini*Cart each have a row of keys above the standard alpha-numeric keys that control archive and review functions. These controls and commands are described in the instructions for each function.

Archive and Review Menu Items

Figure 6-5. **Archive/Review keys**

The Scan Engine has menu items on the Tools Tab that control archive and review functions. The View Current menu item controls functions for in-progress exam review, and the View Archive menu item enables access to previously archived exams stored on the internal CompactFlash.

To View Images in an In-progress Exam (SuperCart or *mini*Cart)

1. Press the **Current Exam** key on the keyboard.

   If no images have been stored, a message displays stating that there is no current exam data.

2. Images in the current in-progress exam are displayed with the most recently stored image displayed first (for example, if 7 images have been stored, images 5, 6, and 7 display).

3. The user can change the display format by pressing the **Format** key (SuperCart or *mini*Cart) on the keyboard.

   Images can be displayed in 1 x 1 format (single full page image), a 2 x 2 format (4 images in 2 rows of 2), or a 3 X 2 format (6 images in 2 rows of 3) with the most recently image displayed first.

4. The user can display the previous full-size image (or previous page of multi-image format images) by pressing the **Pg Back** key on the keyboard. If there is no previous image, pressing the **Pg Back** key does nothing.

5. The user can display the next full-size image (or next page of multi-image format images) by pressing the **Pg Fwd** key on the keyboard.

6. If there is no following image, pressing the **Pg Fwd** key does nothing.

7. The user can display the first or last image in the exam by pressing the **First/Last** key on the keyboard.

   Pressing the **First/Last** key once displays the first image in the exam. Pressing the **First/Last** key again displays the last image in the exam.

8. While in multi-image format, the user can select a specific image to view full-size:
   a. Using the trackball, move the arrow cursor over the desired image.
   b. Press the **Set** key to highlight the image. The image is bordered in green.
   c. Press the **Set** key again to display the full-size image.
   d. Press the **Format** key to return to the previous multi-image format.
9. To exit in-progress exam review press the **Current Exam** key to return to live imaging.

   OR

   Press the **Back** key twice. The first press displays the Current Exam review menu; the second press returns to live imaging.

To View Images in an In-progress Exam (Scan Engine)

1. In the Tools menu, use the Menu Control to scroll to the View Current menu item and press the **Select** key.

   If no images have been stored, a message displays stating that there is no current exam data.

2. Images in the current in-progress exam display in a full-size format with the most recently image stored displayed first (for example, if 7 images have been stored, image 7 displays).

3. To change the display format use the **Menu Control** to scroll to the **Format** menu item. Use the left/right arrow functions of the **Menu Control** to change display formats. Images display in a 2 X 2 format (4 images) with the most recently image stored displayed first.

   Selecting the Format menu item again displays the images in a 3 X 2 format (6 images in 2 rows of 3 images) with the most recently stored image displayed first.

4. To display the previous full-size image (or previous page of multi-image format images) use the **Menu Control** to scroll to the Pg Back menu item and then use the left/right arrow functions of the **Menu Control** to sequence to the full-size image format.

5. To display the next full-size image (or next page of multi-image format images) use the Menu Control to scroll to the Pg Fwd menu item and then use the left/right arrow functions of the **Menu Control**.

6. To display the first or last image in the exam use the Menu Control to scroll to the First or Last menu item and then use the left/right arrow functions of the **Menu Control**.

   Selecting the first menu item displays the first image in the exam. Selecting the last menu item displays the last image in the exam.

7. While in multi-image format, the user can select a specific image to view full-size:

   a. Using the trackball, move the arrow cursor over the desired image.

   b. Press the **Set** key to highlight the image. The image is bordered in green.

   c. Press the **Set** key again to display the full-size image.

   d. Select the Format menu item to return to the previous multi-image format.

8. To play a clip image from review:

   a. Select the Format menu item to return to the previous multi-image format.Using the trackball, move the arrow cursor over the desired

   b. Press the Set key to highlight the image. The image is bordered in green.

   c. Press the Set key again to display the full-size image.

   d. Press Freeze to play the clip. Press Freeze again to stop the clip.

   e. When clip is "frozen", use the trackball to move through individual frames

9. To exit in-progress exam review press the **Back** key to return to live imaging.

   OR

   Using the Menu Control, scroll to the Exit menu item and press the **Select** key. The **z.one** returns to live imaging.

To Open an Archived Exam for Review (SuperCart or *mini*Cart)

1. Press the **Archive** key on the keyboard.

   If no exams have been archived, a message displays stating that there are no exams stored.

2. The Patient Selection Table displays. The Patient Selection Table is a database of all the exams stored on the internal CompactFlash.

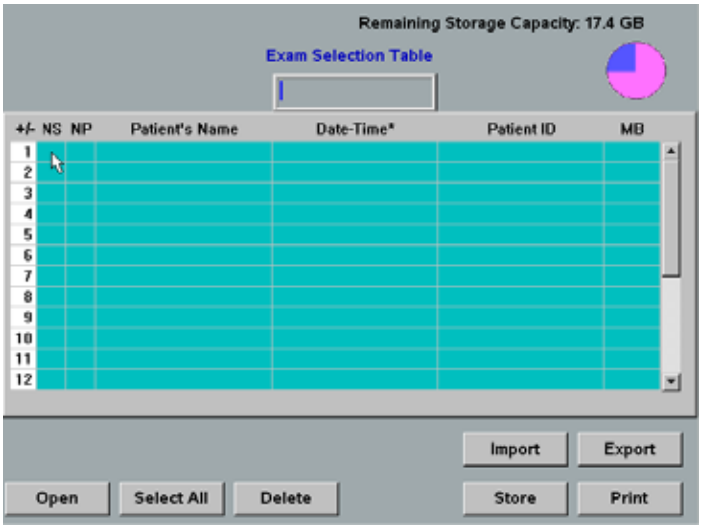


Figure 6-6. **Patient Selection Table**

Exams display alphabetically by Patient Name. Exams in the Patient Selection Table can be sorted by Patient Name, Date, ID, or Size (in megabytes).

3. To define the Exam Selection Table headings:

   a. Using the trackball, move the arrow cursor over the **+/-** heading.

   b. Press the **Set** key, to bring up the **+/-** pull-down menu

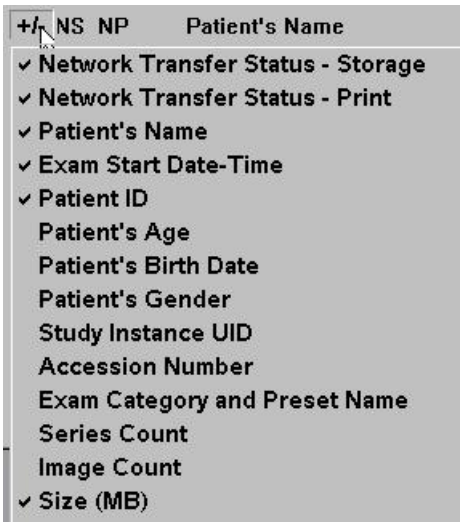


Figure 6-7. **Exam Selection Table Heading Configuration**

c. Place the arrow cursor to the left of the desired parameter(s) from the pull-down menu, and press the **Set** key to check (select) or uncheck (un-select) each item as desired.

4. To select a sort variable:

   a. Using the trackball, move the arrow cursor over the desired column heading.

   b. Press the **Set** key. The Find data field moves over the selected column and the column is noted by an asterisk.

5. Use the keyboard to enter data in the Find field.

6. As data is entered in the Find data field, the sort is refined.

   For example, if the sort is by Patient Name and a T is entered in the Find data field, all names beginning with T display. If an H is added, all names beginning with TH display, etc.

7. To select an exam to open for review:

   a. Using the trackball, move the cursor arrow over the desired exam and press the **Set** key once. The exam is highlighted.

   b. Press the **Set** key again. The images in the exam display.

8. If the wrong exam is selected in step a above:

   a. With the wrong exam still highlighted, move the arrow cursor over the desired exam and press the **Set** key.

      This highlights the desired exam and the wrong exam remains highlighted.

   b. Move the arrow cursor over the wrong exam and press the **Set** key.

      The highlighting is removed from the wrong exam.

   c. Press the **Set** key to open the desired exam and display its images.

To Open an Archived Exam for Review (Scan Engine or *mini*Cart)

1. From the Tools tab, use the Menu Control to scroll to the View Archive menu item and press the **Select** key.

   If no exams have been archived, a message displays stating that there are no exams stored.

2. The Patient Selection Table displays.

Exams display alphabetically by Patient Name. Exams in the Patient Selection Table can be sorted by Patient Name, Date, ID, or Size (in megabytes).

3. To select a sort variable:

   a. Using the trackball, move the arrow cursor over the desired column heading.

   b. Press the **Set** key. The Find data field moves over the selected column and the column is noted by an asterisk.

4. Use the Menu Control to scroll to the Keyboard menu item and press the **Select** key. The VKB displays.

   Use the stylus to press characters on the VKB for entry in the Find data field.

5. As data is entered in the Find data field, the sort is refined.

   For example, if the sort is by Patient Name and a T is entered in the Find data field, all names beginning with T display. If an H is added, all names beginning with TH display, etc.

6. To select an exam to open for review:

   a. Using the trackball, move the cursor arrow over the desired exam and press the **Set** key once. The exam is highlighted.

   b. Press the **Set** key again. The images in the exam display.

7. If the wrong exam is selected in step a above:

   a. With the wrong exam still highlighted, move the arrow cursor over the desired exam and press the **Set** key.

      This highlights the desired exam and the wrong exam remains highlighted.

   b. Move the arrow cursor over the wrong exam and press the **Set** key.

      The highlighting is removed from the wrong exam.

   c. Press the **Set** key to open the desired exam and display its images.

Viewing Images in an Archived Exam

The procedure for viewing images in an archived exam is the same as for viewing images in an in-progress exam, described earlier in this chapter.

To Exit Archived Exam Review (SuperCart or *mini*Cart)

Press the **Archive** key. This returns the **z.one** to live imaging.

OR

Press the **Back** key three times. The first press displays the Review menu. The second press displays the Patient Selection Table.

NOTE: At this point, the user can select another exam for review.

The third press returns the **z.one** to live imaging.

To Exit Archived Exam Review (Scan Engine)

Use the Menu Control to scroll to the Exit menu item and press the **Select** key. This returns the **z.one** to live imaging.

OR

Press the **Back** key three times. The first press displays the Review menu. The second press displays the Patient Selection Table.

NOTE: At this point, the user can select another exam for review.

The third press returns the **z.one** to live imaging.

Deleting Images and Exams

The user can delete images from in-progress exams and from archived exams. The procedure is the same for in-progress exams and for archived exams.

The user can delete archived exams from the internal CompactFlash. The user can delete a single exam, multiple exams, pages of exams, or all exams on the internal CompactFlash.

WARNING: Once deleted, exams cannot be restored. Their data is lost.

To Delete Images (SuperCart or *mini*Cart)

1. Enter in-progress exam review or select and open an archived exam, as described earlier in this chapter.
2. To select an image for deletion in a multi-image format, use the trackball (trackball on the Scan Engine, in *mini*Cart configuration of the **z.one**) to move the arrow cursor over the desired image and press the **Set** key to highlight it.
3. Press the **Delete** key on the keyboard. A red **X** is drawn across the image.
4. Multiple images, up to the total number of images in the exam, can be tagged for deletion by repeating steps 2 and 3.

5. To delete a full-size image, press the **Delete** key. A red **X** is drawn across the image.

6. Multiple full-size images can be tagged for deletion by using the Pg Back and Pg Fwd keys to select the desired images and then pressing the **Delete** key.

7. To untag an image for deletion, select an image with a red **X** through it and press the **Delete** key.

   The red **X** is removed.

8. To complete the delete operation, exit in-progress review or archived image review as described earlier in this chapter.

9. A message requiring confirmation to delete the desired number of images displays.

10. Press the **Select** key to answer Yes.

11. The images are deleted and the **z.one** returns to live imaging.

    If the user opens an in-progress exam or the archived exam for review again, the deleted images are replaced by other images in the exam so that there are no blank spaces.

To Delete Images (Scan Engine)

1. Enter an in-progress exam review or select and open an archived exam, as described earlier in this chapter.

2. To select an image for deletion in a multi-image format, use the trackball to move the arrow cursor over the desired image and press the **Set** key to highlight it.

3. Use the Menu Control to scroll to Delete and press the **Select** key. A red **X** is drawn across the image.

4. Multiple images, up to the total number of images in the exam, can be tagged for deletion by repeating steps 2 and 3.

5. To delete a full-size image, use the Menu Control to scroll to Delete and press the **Select** key.

   A red **X** is drawn across the image.

6. Multiple full-size images can be tagged for deletion by using the **Pg Back** and **Pg Fwd** keys to select the desired images and then selecting the **Delete** key.

7. To untag an image for deletion, select an image with a red **X** through it and use the Menu Control to scroll to Delete and press the **Select** key.

   The red **X** is removed.

8. To complete the delete operation, exit in-progress review or archived image review as described earlier in this chapter.

9. A message requiring confirmation to delete the desired number of images displays.

10. Press the **Select** key to answer Yes.

11. The images are deleted and the **z.one** returns to live imaging.

    If the user opens an in-progress exam or the archived exam for review again, the deleted images are replaced by other images in the exam so that there are no blank spaces.

To Delete Single or Multiple Exams (SuperCart or *mini*Cart)

1. Press the **Archive** key on the keyboard to display the Patient Selection Table.

2. Use the trackball (trackball on the Scan Engine, in *mini*Cart configuration of the **z.one**) to move the arrow cursor over the desired exam and press the **Set** key to highlight the exam.

3. Move the arrow cursor over the Delete soft key and press the **Set** key.

4. The **z.one** displays a message requiring confirmation to delete the exam.

5. Press the **Select** key to answer Yes.

6. The exam is deleted and the Patient Selection Table is refreshed to leave no blank rows.

7. Multiple exams can be deleted by repeating step 2 until all the desired exams have been highlighted for deletion.

To Delete Pages of Exams (SuperCart or *mini*Cart)

The currently displayed page of exams can be deleted.

1. Press the **Archive** key on the keyboard to display the Patient Selection Table.
2. Use the trackball (trackball on the Scan Engine, in *mini*Cart configuration of the **z.one**) to scroll to the desired page.
3. Move the arrow cursor over the Delete Page soft key and press the **Set** key.
4. All the exams on the currently displayed page is highlighted and the **z.one** displays a message requiring confirmation to delete the exams.
5. Press the **Select** key to answer Yes.
6. The page of exams is deleted and the Patient Selection Table is refreshed to leave no blank rows.

To Delete All Exams (SuperCart or *mini*Cart)

1. Press the **Archive** key on the keyboard to display the Patient Selection Table.
2. Use the trackball (trackball on the Scan Engine, in *mini*Cart configuration of the **z.one**) to move the arrow cursor over the Delete All soft key and press the **Set** key.
3. All the exams on the Patient Selection Table are highlighted and the **z.one** displays a message requiring confirmation to delete the exams.
4. Press the **Select** key to answer Yes.
5. All exams are deleted, displaying a blank Patient Selection Table.

Deleting Single or Multiple Exams (Scan Engine)

1. From the Tools Tab menu, use the Menu Control to scroll to View Archive and press the **Select** key to display the Patient Selection Table.
2. Use the trackball to move the arrow cursor over the desired exam and press the **Set** key to highlight the exam.
3. Use the Menu Control to scroll to Delete and press the **Select** key.
4. The **z.one** display a message requiring confirmation to delete the exam.
5. Press the **Select** key to answer Yes.

6. The exam is deleted and the Patient Selection Table is refreshed to leave no blank rows.

7. Multiple exams can be deleted by repeating step 2 until all the desired exams have been highlighted for deletion.

8. Use the Menu Control to scroll to Delete and press the **Select** key.

9. The **z.one** displays a message requiring confirmation to delete the exams.

10. Press the **Select** key to answer Yes.

11. The exams are deleted and the Patient Selection Table is refreshed to leave no blank rows.

Deleting Pages of Exams (Scan Engine)

The currently displayed page of exams can be deleted.

1. From the Tools Tab menu, use the Menu Control to scroll to View Archive and press the **Select** key to display the Patient Selection Table.

2. Use the trackball to scroll to the desired page.

3. Use the Menu Control to scroll to Delete Page and press the **Select** key.

4. All the exams on the currently displayed page are highlighted and the **z.one** displays a message requiring confirmation to delete the exams.

5. Press the **Select** key to answer Yes.

6. The page of exam is deleted and the Patient Selection Table is refreshed to leave no blank rows.

To Delete All Exams (Scan Engine)

1. From the Tools Tab menu, use the Menu Control to scroll to View Archive and press the **Select** key to display the Patient Selection Table.

2. Use the Menu Control to scroll to Delete All and press the **Select** key.

3. All the exams on the Patient Selection Table are highlighted and the **z.one** displays a message requiring confirmation to delete the exams.

4. Press the **Select** key to answer Yes.

5. All exams are deleted, displaying a blank Patient Selection Table.

Storing Archived Exams to DICOM Devices (SuperCart or *mini*Cart)

The **z.one** can store archived exams to configured DICOM storage devices. This might be required if the Scan Engine has been used to perform exams while in the standalone mode, or if the DICOM network experienced connectivity problems.

To Store Archived Exams to DICOM Storage Devices:

1. Press the **Archive** key on the keyboard to display the Patient Selection Table.
2. Use the trackball (on the Scan Engine, in *mini*Cart configuration of the **z.one**) to move the arrow cursor over the desired exam and press the **Set** key to highlight the exam.
3. Move the arrow cursor over the **Store** soft key and press the **Set** key.
4. Verify that the target destination network storage device is correct (select desired device is not current selected).
5. Move the arrow cursor over the **Store** soft key and press the **Set** key.
6. The selected exam is stored to the DICOM storage device.

   This is done in the background, so the **z.one** can be operated normally while the transfer is taking place.

Restarting an Exam

An exam that has been started within the current calendar day can be restarted. Previous Calc data, demographic data, and images in the restarted exam are available, as with a New exam. Any newly stored images, clips, and data is added to the restarted exam.

To Restart an Exam (SuperCart)

1. Open the Patient Information form.
2. Use the trackball to move the arrow cursor over the **Restart** soft key and press the **Set** key.
3. A list of exams (similar to the Patient Selection Table) that have been opened during the current calendar day displays.

4. Place the arrow cursor over the desired exam and press the **Set** key to highlight the exam.

5. Press the **Set** key a second time to open the exam.

   OR

   Move the arrow cursor over the Select Exam soft key and press the **Set** key to open the exam.

   The Patient Information page displays, populated with patient demographics data from the restarted exam. The user can continue the exam as with a new exam.

To Restart an Exam (Scan Engine or *mini*Cart)

1. Open the Patient Information form.

2. Use the Menu Control to scroll to the Restart Exam menu item and press the **Select** key.

3. A list of exams, similar to the Patient Selection Table, that have been opened during the current calendar day displays.

4. Use the trackball to place the arrow cursor over the desired exam and press the **Set** key to highlight the exam.

5. Press the **Set** key a second time to open the exam.

   OR

   Move the arrow cursor over the Select Exam soft key and press the **Set** key to open the exam.

   The Patient Information page displays, populated with patient demographics data from the restarted exam. The user can continue the exam as with a new exam.

Annotations and Measurements on In-progress Exams and Archived Exams

The user can enter annotations and perform measurements on in-progress exams and restarted (within the same calendar day) exams. To save Annotations and Measurements, the user must freeze the image and press **Store**. Otherwise, the data is lost when exiting in-progress review or closing a restarted exam.

The user can perform measurements on images in archived exams that were started before the current calendar day. However, these measurements cannot be saved. The data is lost when exiting the review session. Annotations cannot be entered on images in exams started before the current calendar day.

Importing/Exporting of Exams: USB Memory Sticks

Exam data (images) can be moved in / out of the **z.one**, using the "IMPORT" and "EXPORT" functions. Exam data (images) can be moved from internal CompactFlash to an externally connected USB Memory Stick ("EXPORT"), or vice-versa ("IMPORT").

To EXPORT Exams: (from internal CompactFlash, to USB Memory Stick)

1. Insert an image storage USB Memory Stick into the USB port on the **z.one**.

2. Press the **ARCHIVE** key (SuperCart or *mini*Cart), or the **VIEW ARCHIVE** selection in the Toolbar menu on the Scan Engine, to view the main ARCHIVE page.

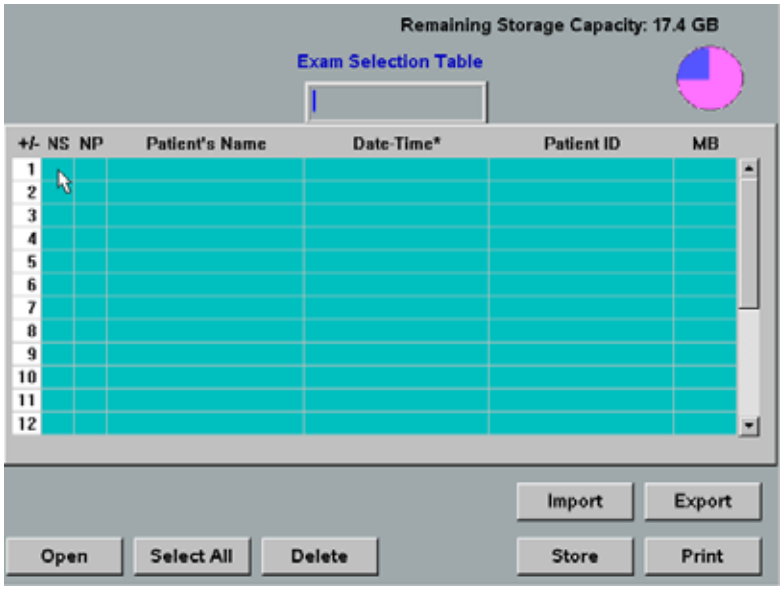


Figure 6-8. **ARCHIVE Main Menu (EXPORT - IMPORT Option)**

3. Use the trackball to move the arrow cursor over the **EXPORT** softkey, and press the **Set** key to open the main EXPORT page.

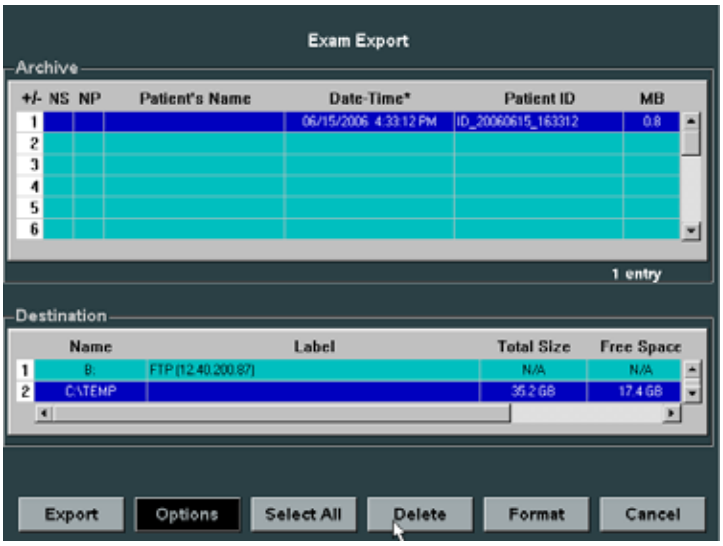


Figure 6-9. **EXPORT Main Menu**

4. Use the trackball and **Set** key to highlight the target Destination device (USB Memory Stick) in the **Destination** table.

5. Use the trackball and **Set** key to highlight the exam(s) on the internal **Archive** list that is(are) desired to be Exported to the target Destination device (USB Memory Stick).

NOTE: Multiple exams can be selected (highlighted) by using the same method. All exams can be selected (Highlighted) by clicking on the **Select All** key. Once the exam(s) are selected, they can be "unselected" by clicking on them a second time.

6. Use the trackball and **Set** key to select the **EXPORT** softkey, to initiate the download (import) of the selected exam(s) to internal CompactFlash archive.

7. A message appears when the **IMPORT** task is completed.

8. The imported exams can now be reviewed, from internal CompactFlash, via the **ARCHIVE** menu on the **z.one**. Use the trackball and **Set** key to select the **EXPORT** softkey, to initiate the transfer (export) of the selected exam(s) to the Destination device (USB Memory Stick).

- Selected exams on the external USB Memory Stick can be deleted by highlighting them (with the trackball and **Set** key) and using the **DELETE** softkey on the Exam Export screen.

- The external USB Memory Stick can be formatted (all contents erased) using the FORMAT softkey in the Exam Export screen.

NOTE: The FORMAT function may not be fully functional in the initial 2.0 software release.

EXPORT Options

The Exam Export Option menu allows for customizing the format of the exam data that will be exported to the external USB Memory Stick. This formatting includes compression type and color mapping method that can be set to match the requirements for the final usage of the image files (PC, PACS device, etc).

In addition, the Exam Export Option menu provides the ability to filter out all proprietary patient identity information, and/or thumbnail images, from the exported exam data.

1. From the main EXPORT page, use the trackball and **Set** key to select the **OPTIONS** softkey.

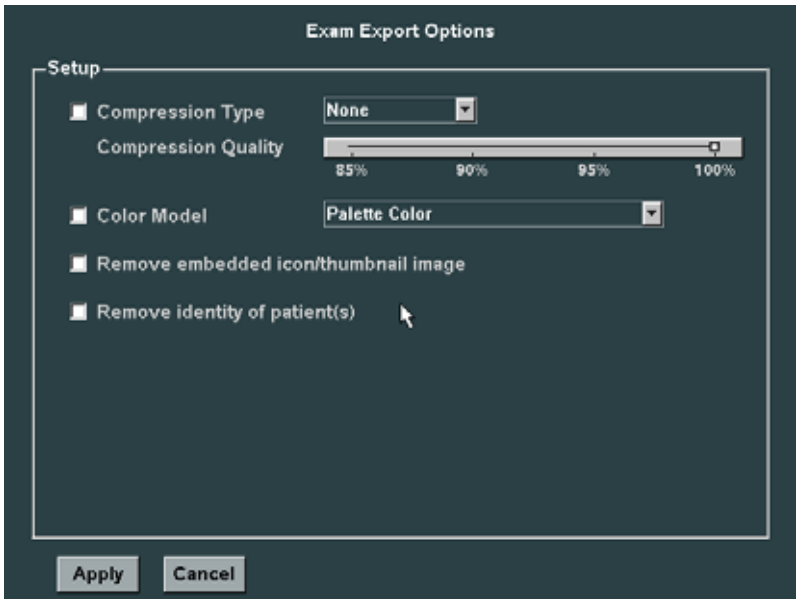


Figure 6-10. **EXPORT "Options" Menu**

2. Using the trackball and **Set** key, make the desired selections on the Exam Export Options screen, and then select **APPLY** to save the new settings.

To IMPORT Exams: (to internal CompactFlash, from an External USB Device

1. Insert an image storage USB Memory Stick into the USB port on the **z.one**.

2. Press the **ARCHIVE** key (SuperCart or *mini*Cart), or the **VIEW ARCHIVE** selection in the Toolbar menu on the Scan Engine, to view the main ARCHIVE page.

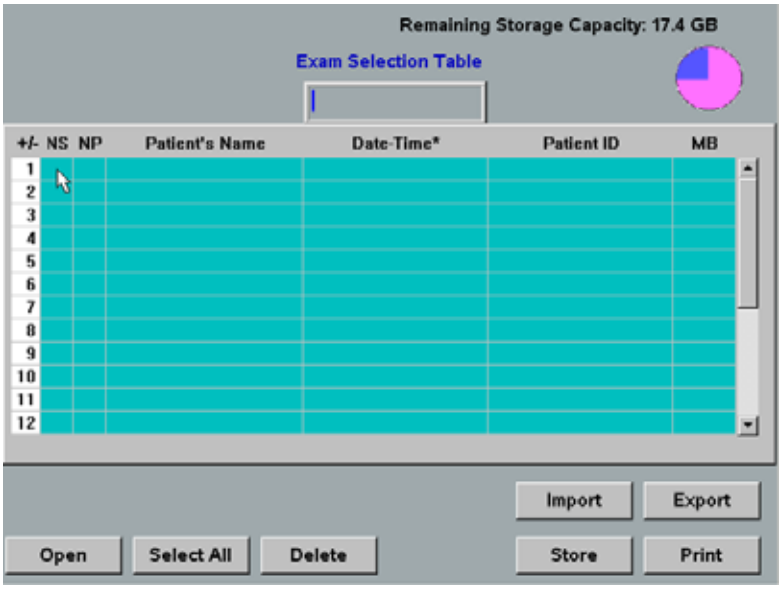


Figure 6-11. **ARCHIVE Main Menu (EXPORT - IMPORT Option)**

3. Use the trackball to move the arrow cursor over the **IMPORT** softkey, and press the **Set** key to open the main IMPORT page.

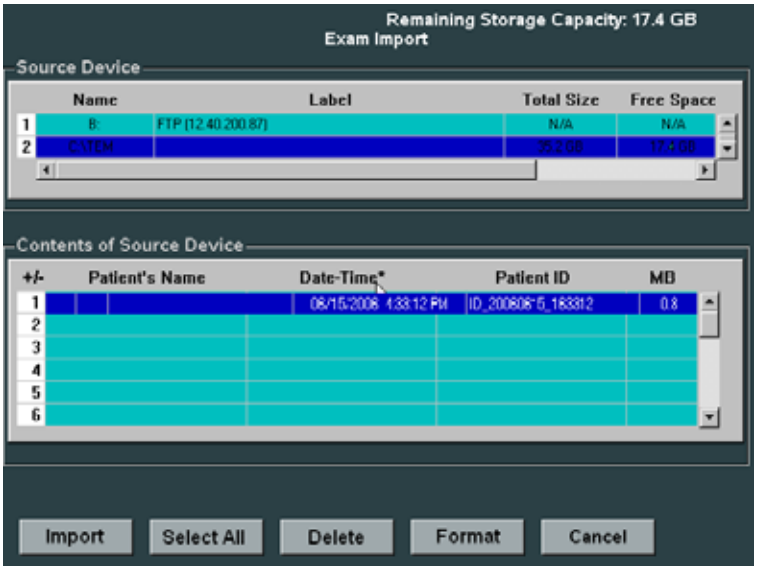


Figure 6-12. **IMPORT Main Menu**

4. Use the trackball and **Set** key to highlight the desired source device (USB Memory Stick) in the **Source Device** table.

5. The contents (exams) of the selected source device will populate in the **Contents of Source Device** list.

6. Use the trackball and **Set** key to highlight the exam(s) on the internal **Contents of Source Device** table that is(are) desired to be Imported from the target USB device (USB Memory Stick).

NOTE: Multiple exams can be selected (highlighted) by using the same method. All exams can be selected (Highlighted) by clicking on the **Select All** key. Once the exam(s) are selected, they can be "unselected" by clicking on them a second time.

7. Use the trackball and **Set** key to select the **IMPORT** softkey, to initiate the download (import) of the selected exam(s) to internal CompactFlash archive.

8. A message appears when the **IMPORT** task is completed.

9. The imported exams can now be reviewed, from internal CompactFlash, via the **ARCHIVE** menu on the **z.one**.

Emergency Backup System Data: (from internal CompactFlash, to an External USB Memory Stick)

1. Remove the scan engine from its docking location, and open up the LCD display for viewing.

2. Insert the desired target USB Memory Stick into the USB port on the **z.one**.

3. Ensure the scan engine is initially powered off.

4. Press the power button on the scan engine, and then immediately upon seeing the splash screen graphics appear on the display (approximately 4 seconds), press the **BACK** button on the scan engine to perform a *user-break* of the normal boot-up sequence.

5. In the user-break menu, press the **F1** button on the scan engine to initiate the Backup of System Data (contents of internal CompactFlash) to the USB Memory Stick.

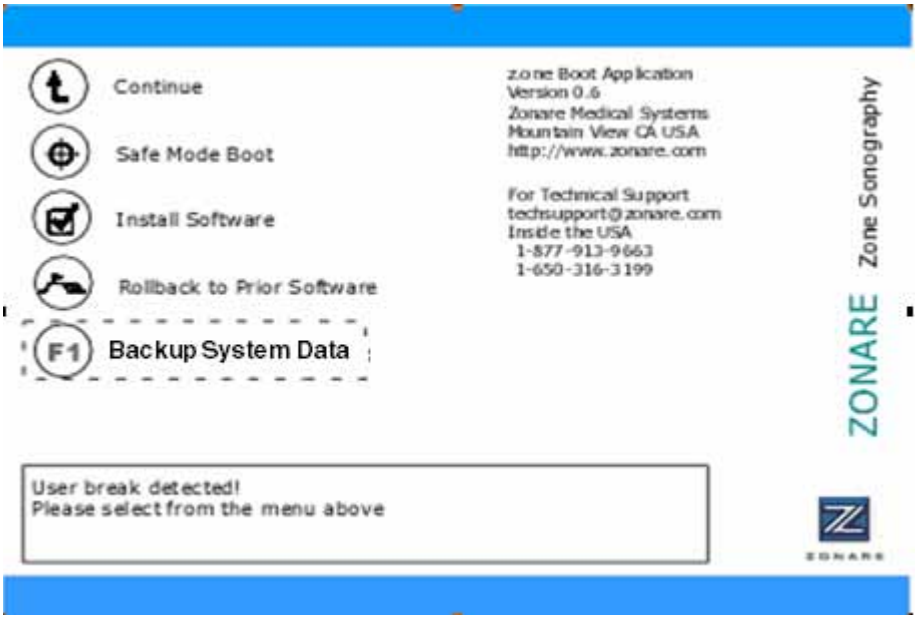


Figure 6-13. **User-Break Screen - Internal CF Porting to USB Memory Stick**

7

Peripherals

This chapter will provide basic operating instructions for use of peripheral devices that are sold by Zonare (as an option) for use on the **z.one**:

SuperCart:

- Sony UP-897MD Black & White Video Printer
- Sony UP-21MD Color Video Printer
- Panasonic LQ-MD800 DVD Video Recorder

***mini*Cart:**

- Sony UP-D897 Digital (USB 2.0) Black & White Printer

WARNING: Peripheral devices not sold and/or authorized by Zonare for use on the **z.one** should **not** be used. Zonare is not responsible for any problems or damage that may result from connection of such unauthorized devices to the **z.one**.

The information in this chapter is only intended to provide basic operating instructions for the peripheral devices sold for use on the **z.one**. For more detailed information on operation or setup for any of these peripheral devices, please refer to the manufacturers instruction manual (provided by Zonare at the time of shipment, for each peripheral device).

Sony UP-897MD B&W Video Printer

Figure 7-1. **Sony UP-897MD B/W Video Printer**

Setup:

NOTE: The following section assumes that the Sony UP-897MD B/W Video Printer has already been mounted to the chassis of the **z.one**, and had the power, video and remote trigger cables properly connected. For information on installation/hook-up, please refer to the ***Proc, Installation, Sony UP-897MD B/W Printer*** (Zonare P/N: ***S00031***) document that is provided in the installation kit shipped from Zonare with each printer. This information is also provided in the Z.ONE Service Manual.

1. Power on the **z.one** and allow it to fully boot.
2. Select **Tools | System Setup | Archive** | **Print/Store** |, to access the Print and Store key configuration menu.
3. Configure the **Print** key on the SuperCart for "**VIDEO PRINTER**" function, to enable an external trigger to be activated to remotely trigger a print on the Sony UP-897MD unit

NOTE: Optionally, the **Store** key may also (or) be configured in this same menu to be used for triggering video prints by the Sony UP-897MD

4. Open the front door of the unit, and install the film pack.
5. Power on the UP-897MD, by pressing the Power-On button on the front panel.

Operation:

1. Acquire the desired ultrasound image on the z.one.
2. Press the “FREEZE” key on the z.one, to obtain a static image.
3. Press the “PRINT” button to trigger a print of the current on-screen image to the UP-897MD.

Sony UP-21MD Color Video Printer.

Figure 7-2. **Sony UP-21MD Color Video Printer**

1. Power on the **z.one** and allow it to fully boot.
2. Select **Tools | System Setup | Archive** | **Print/Store** |, to access the Print and Store key configuration menu.
3. Configure the **Print** key on the SuperCart for "**VIDEO PRINTER**" function, to enable an external trigger to be activated to remotely trigger a print on the Sony UP-21MD unit.

NOTE: Optionally, the **Store** key may also (or) be configured in this same menu to be used for triggering video prints by the Sony UP-21MD.

4. Open the film tray (located at the front of the Sony UP-21MD), and install the film pack.
5. Power on the UP-21MD, by pressing the Power-On button on the front panel.

Operation:

1. Acquire the desired ultrasound image on the z.one.
2. Press the “FREEZE” key on the z.one, to obtain a static image.
3. Press the “PRINT” button to trigger a print of the current on-screen image to the UP-21MD.

Panasonic LQ-MD800 DVD Video Recorder

Figure 7-3. **Panasonic LQ-MD800 DVD Video Recorder**

NOTE: The following section assumes that the Panasonic LQ-MD800 DVD recorder has already been mounted to the **z.one**, and all cabling between the two units has been properly connected. For information on installation/hook-up, please refer to the ***Proc, Installation, Panasonic LQ-MD800 DVD*** (Zonare P/N: ***S00074***) document that is provided in the mounting kit which is shipped from Zonare with each DVD recorder. This mounting/connection information is also provided in the Z.ONE Service Manual.

1. Power on the **z.one** and allow it to fully boot.

2. Select **Tools | System Setup | Function Keys**|, to access the function key configuration menu. Configure the **F1** key on the SuperCart for "**EXT SYNC**" function, to enable an external trigger to be activated to remotely pause/release the Panasonic LQ-MD800 unit.

Recording:

1. Power on the LQ-MD800, and insert a blank DVD-R- into the unit.

2. To setup a video recording session, while scanning a patient on the **z.one**, place the LQ-MD800 into the record mode by using the controls on the unit.

3. To start recording, press the "**F1**" key on the SuperCart, to un-pause the LQ-MD800.

Finalizing (Burning) DVD For Viewing:

NOTE: Prior to a DVD-R being ready for playback (viewing) use, the content must be permanently burned into the DVD-R. This process is called "***Finalizing***", and is performed on the LQ-MD800 by executing the following steps.

1. Using the "**Ext Video**" key on the SuperCart, enable video output from the DVD recorder to be displayed on the SuperCart's Barco LCD monitor.

2. Press **Shift** & **Menu** on LQ-MD800 player.

3. Go to the Disk Information screen, using the arrow keys (menu displays on **z.one** monitor).

4. Choose the "**Finalize**" selection from the menu.

NOTE: The "Finalize" process can take up to 14 minutes to complete. The required time is inversely proportion to the amount of recorded data on the DVD-R.

5. The DVD-R can now be removed from the LQ-MD800, and played (viewed) by inserting it into the DVD reader on any PC or similar device.

Sony UP-D897 Digital (USB 2.0) B&W Printer (*mini*Cart)

Figure 7-4. **Sony UP-D897 B&W USB Printer**

NOTE: The following section assumes that the Sony UP-D897 B&W USB Printer has already been mounted to the chassis of the z.one *mini*Cart, and had the power and USB cable properly connected. For information on installation/hook-up, please refer to the ***Proc, Installation, Sony UP-D897 B&W USB Printer*** (Zonare P/N: ***S00032-00***) document that is provided in the installation kit shipped from Zonare with each printer. This information is also provided in the **z.one** Service Manual

1. Power on the **z.one** and allow it to fully boot.

2. Open the front door of the unit, and install the film pack.

3. Power on the UP-D897, by pressing the Power-On button on the front panel.

Operation:

1. Acquire the desired ultrasound image on the z.one.
2. Press the “FREEZE” key on the z.one, to obtain a static image.
3. Depending upon the Print/Store key configuration, press the appropriate button (“PRINT” or “STORE”) on the Scan Engine, to trigger a print of the current on-screen image, to the UP-D897 printer.

8

DICOM Connectivity

Configuring DICOM

For Customer's systems that have activated (purchased) the optional DICOM module, the **z.one** is capable of exchanging data with DICOM-compliant archive devices, output devices, and worklist applications over the institution network. For each such device, a connection must be configured on the **z.one**, using the correct DICOM configuration screen(s).

WARNING: To prevent the need for manually repeating the configuration of all the **DICOM** and general ***System*** parameters into the **z.one** (in the case of replacement of the Scan Engine or a complete "clean" software installation) a **Backup System** operation (to USB Memory Stick) should be performed immediately upon completion of the configuration process. Refer to "To Backup "SYSTEM" configuration to USB Memory Stick" on page 3-9 for instructions on performing this backup operation.

The following five (5) DICOM configuration screens are offered on the **z.one**.

- **General**
- **Printers**
- **Network Store**
- **MPPS**
- **Worklist**

The parameters in the "General" configuration screen will require setup for all types of DICOM connections (Printer, Storage, etc.). The number of additional configuration screen(s) requiring configuration will be dictated by the type of DICOM device(s) that will be attached to the **z.one**.

In addition to the setup of the DICOM configuration menus, the **Store** and **Print** keys on both the SuperCart and the Scan Engine must be configured for their assignment in sending data from the **z.one** to different storage and

output devices, or sets of devices. Refer to "To configure the Store and Print button functions" on page 8-18.

In order to perform all functions, an active network connection to the target DICOM device(s) must be present during the DICOM configuration process. When the network connection is live, the network icon in the Image area on the **z.one** is shown as active.

Figure 8-1. **Network Icon Active and Inactive**

NOTE: Once all of the DICOM parameters have been configured into the required DICOM setup menus, or any parameters are edited in an existing configuration, it will be necessary to power down and reboot the **z.one** in order to initialize the new network connections with the target devices.

DICOM menu

Figure 8-2. **DICOM Menu**

View the DICOM configuration screens from the **DICOM** menu.

To access the main DICOM Menu

Select **Tools | System Setup | DICOM**.

DICOM Configuration Parameters

Configuring a DICOM connection requires some specific data about the **z.one**, about the device to be configured, and about the network. Refer to the following table. Zonare recommends that department staff collaborate with a network administrator to assemble the necessary data and enter it correctly on the DICOM configuration screens. The following table provides some guidance regarding the information required for the DICOM configuration of the **z.one**.

DICOM Configuration Parameters	
AE Title e.g., "Zonare"	The official "name" (*Application Entity*) assigned to the Z.ONE (by the network administrator) to identify it to the network.
Compression: None RLE Lossless JPEG Lossy	Enables selecting a method (RLE Lossless) for temporary coding of data in a way that compresses the image files during transfer. Compression saves storage space and reduces file transfer times. **RLE Lossless** compression protocol automatically reduces the size of the transferred image, yet retain all source content. **JPEG Lossy** compression protocol allows for the greatest level of file size reduction (compression). Quality(85-100%) is a user configurable parameter for this compression type, and determines the resultant compressed file size.
Date Range	Specify the number of days back (Today, 2, 7, All) that the DICOM worklist will reference scheduled examinations.
Gateway IP Address	For connections to target DICOM devices on a network using a gateway, this is a required TCP/IP parameter that must be entered (i.e. 128.0.0.1)
ICON Image	A sub-sampled (miniature size, thumbnail) version of the image created for each patient image on the **Z.ONE**. Options are to either *retain* or *remove* these images from DICOM image transfers to the target device. (default is "*retain*")
IP address	Internet Protocol address. The Internet address of a computer attached to an IP network (TCP/IP network). Consult a network administrator.
Keep Alive Timeout	Specify the duration (in seconds) that an established DICOM connection will be maintained, after completion of the last transfer.

DICOM Configuration Parameters	
Limit by Modality None US (ultrasound 50+ additional options: (see list provided)	Filter the Worklist by modality (US, CT, MRI, et cetera). Set according to department requirements. None: Show entries for *all* modalities. US: Show entries for ***ultrasound*** exams only. The following additional modality filter (limit) settings are available for selection: Selections - AU, BI, CD, CR, CT, DD, DG, DX, ECG, EPS, ES, FID, GM, HC, HD, IO, IVUA, KO, LS, MG, MR, NM, OP, OT, PR, PT, PX, REG, RF, RG, RTDOSE, RTIMAGE, RTPLAN, RTRECORD, RWV, SM, SMR, SR, ST, TG, US, XA, XC
Log Level	Defines the level of detail information displayed in the DICOM Queue. Consult a network administrator.
Maximum entries cached Enter a number between 0 and 999	Used forWorklists. Set according to department requirements. A higher number provides access to more scheduled exams, but increases the time required to search for the exam of interest.
Min / Max Film Density	For defining Printer density control. Minimum / Maximum density of images on film. Value entered is expressed in hundredths of OD (optical density). A value entered of 150, corresponds with 1.5 OD. Typically acceptable values for dry laser printers is 0-399.
Network Type	Allows for configuring the Z.ONE's network speed and duplex level to either utilize auto-negotiation or be set manually (static) to the requirements of the local network. Selections include: - Auto Negotiate - 100MB / Full Duplex - 100MB / Half Duplex - 10MB / Full Duplex - 10MB / Half Duplex
Network Usage Type	Defines when DICOM images are put into the Queue and transferred to the PACS storage device over the network. Selections include: - Exam in Progress (sends each STORE push) - Exam Completed (sends all at End Exam)
Nickname e.g., "ER Room Printer"	An informal name to identify the device to users in the department. This name is typically assigned in the department.

DICOM Configuration Parameters	
Object Type	Allows for specifying the type of store operation (Still images only, or Still & Clip Store sequences) will be sent over the DICOM network connection to a PACS storage device. NOTE: Installation sites with DICOM PACS storage devices that do ***not*** accept clips, MUST be configured for still image store only.
PDU Receive / Send Size	The size (in bytes) of the basic data packets (PDU: Process Data Unit) that will be transferred during receive and transmit operations. (default is 16384 = 16K)
Polling Interval (minutes) None Choose minutes	The frequency of automatic updates to the worklist. A short polling interval may impact system performance. Choose a preferred interval; or choose **None** to update the worklist only on demand.
Port number	The TCP / IP port number that is being used by the DICOM device connected to the **Z.ONE**. Default port value is 104.
Photometric Interpretation	Defines the method that will be used (Grayscale, RGB color, etc.) by the receiving device (DICOM PACS system) for interpreting the different bit level values of the data, within the transferred images Selections include: - Palette Color - True Color (RGB) - Color by Pixel - True Color (RGB) - Color by Plane - Grayscale (Monochrome2)
Queue Timeout (sec)	The maximum amount of time that a DICOM job will remain active in the queue, before it times out.
Queue Start Type	Defines whether images stored to the DICOM Queue are immediately transferred to the target storage device (*automatic*), or whether images are queued up only, awaiting a manually (User) initiated “Start” of transfer at a later time (*manual*).
Release Association	Specifies whether to release the DICOM association (communication link between the **Z.ONE** and the DICOM storage device) after each individual image is transferred or maintain it until the entire exam is completed.
Scheduled Station AE Title	Filter the Worklist by scheduled station Application Entity (AE) title. Set according to department requirements.

DICOM Configuration Parameters	
Station Name	The TCP/IP "*HOST*" name that will be assigned to the **Z.ONE** for identification on the local network. Should be provided by the Network Administrator.
Subnet Mask	The number of bits (within the 24-bit IP Address) that will be used for defining the "Network" portion vs. the "Host" portion.
TCP Timeout (sec)	The maximum duration (in seconds) of waiting time that will be allowed for completion of TCP transfers over the network. Set according to anticipated network type/speed.

DICOM Pre-Installation Survey Form

In order to ensure that the DICOM configuration process on the **z.one** can be performed as seamlessly as possible, a "Pre-Installation Survey Form" (Zonare part number: F00044) is provided (by Zonare) prior to product shipment to the site. Source information necessary to complete all required fields in this form should be acquired from the Network Administrator (or DICOM device contractor) at the target site prior to performing attempting to configure the parameters in the DICOM setup menus on the **z.one.**

An example of the DICOM portion of this "Pre-Installation Survey Form" is provided on the following pages.

Pre-Installation Survey Form (DICOM Config - Page 1):

Network Setup Parameters

Required	IP Address acquisition method	☐ Obtain Automatically (DHCP) ☐ Use Specified	
Required	Use Specified (IP Address, if fixed)		
Required	Gateway IP Address		
Required	Subnet Mask		
Required	Ethernet MediaType (Speed/Duplex)	☐ Auto-Negotiate ☐ 100MB / Full-Duplex ☐ 100MB / Half-Duplex ☐ 10MB / Full-Duplex ☐ 10MB / Half-Duplex	*Auto Negotiate*

General System / DICOM$_{\text{by Merge}}$ Setup Parameters

Level	Parameter Name	User Site Value/Setting	Default / Special Info
User option	DICOM Application Title		*ZONARE*
User option	Station Name		*ZONARE*
User option	TCP Timeout (sec.)		*30*
User option	Queue Timeout (sec.)		*120*
User option	Queue Start Type	☐ **Automatic** ☐ Manual	*Automatic*
User option	Keep Alive Timeout (sec.)		*3600*
User option	Log Level	☐ None ☐ **Normal** ☐ Debug	*Normal*

Printers (DICOM$_{\text{by Merge}}$) Setup Parameters (if applicable)

Printer Make (Brand): _____ **Printer Model:** _____

Level	Parameter Name	User Site Value/Setting	Default / Special Info
Required	Printer Nickname		
Required	Printer AE Title		
Required	IP Address (Printer)		
Required	Port Number		*104*
User option	Max PDU Receive Size		*16384*
User option	Max PDU Send Size		*16384*
User option	Color Mode	☐ **Color** ☐ Grayscale	*Color*
User option	Number of Copies		*1*
User option	Print Priority	☐ Low ☐ **Med** ☐ High	*Med*
User option	Film Medium	☐ Paper ☐ **Blue Film** ☐ Clear Film	*Blue Film*
User option	Film Orientation	☐ **Portrait** ☐ Landscape	*Portrait*
User option	Film Size	Selections: (**8x10in**, 8.5x11in, 10x12in, 10x14in, 11x14in, 11x17in, 14x14in, 14x17in, 24x24cm, 24x30cm, A4, A3)	*8x10in*
User option	Trim	☐ **Yes** ☐ No	*Yes*
User option	Image Display Format	Selections: (**2x2**, 1x1, 1x2, 2x1, 2x3, 3x2, 3x3, 3x4, 3x5, 4x3, 4x4, 4x5, 4x6, 5x4, 5x5, 5x6, 5x7)	*2x2*
User option	Images Per Page	Selections: (1, 2, 4, 6, **9**, 12, 20, 25)	*9*
User option	Min Film Density		
User option	Max Film Density		
User option	Border Density		*Black*
User option	Empty Image Density		*Black*
User option	Magnification Type	☐ None ☐ Replicate ☐ Bilinear ☐ **Cubic**	*Cubic*
User option	Smoothing Type		

Pre-Installation Survey Form (DICOM Config - Page 2):

Network Store (DICOM$_{by\ Merge}$) Setup Parameters (if applicable)

PACS Device Make (Brand): _____ Device Model: _____ OS Software Rev: _____

Level	Parameter Name	User Site Value/Setting	Default / Special Info
Required	Network Storage Nickname		
Required	Network Storage AE Title		
Required	IP Address (Network Storage)		
Required	Port Number		*104*
User option	Max PDU Receive Size		*16384*
User option	Max PDU Send Size		*16384*
User option	Photometric Interpretation	☐ Palette Color ☐ Grayscale ☐ True Color (RGB) – Color-By-Pixel ☐ True Color (RGB) – Color-By-Plane	*Palette Color*
User option	ICON Image	☐ Retain ICON Image ☐ Remove ICON Image	*Retain ICON Image*
User option	Object Type	☐ Store still image and cine images ☐ Store still images only	*Still and Cine Images*
User option	Release Association	☐ After storing each image in the exam ☐ After storing the entire exam	*After storing each image*

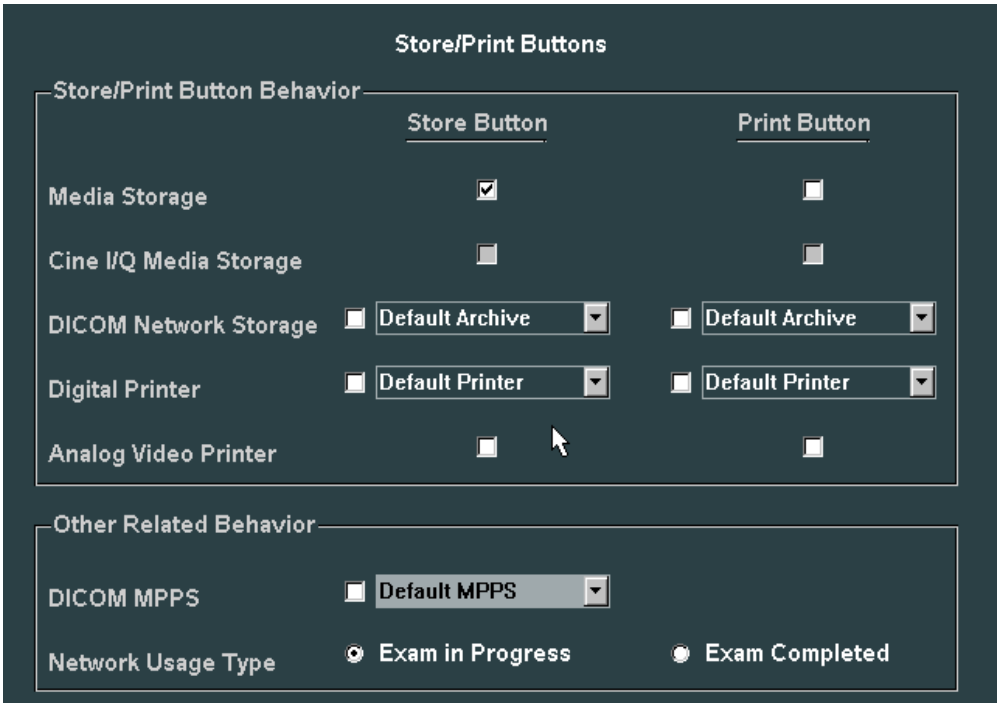
Worklist (DICOM$_{by\ Merge}$) Setup Parameters (if applicable)

Level	Parameter Name	User Site Value/Setting	Default / Special Info
User option	Worklist Server AE Title		*Worklist*
Required	IP Address		
Required	Port Number		*104*
User option	Max PDU Receive Size		*16384*
User option	Max PDU Send Size		*16384*
User option	Date Range	☐ **Today** ☐ Last 2 Days ☐ Last 7 Days ☐ All	*Today*
User option	Limit By Modality	☐ **US** ☐ None Selections – Circle one if desired: (AU, BI, CD, CR, CT, DD, DG, DX, ECG, EPS, ES, FID, GM, HC, HD, IO, IVUA, KO, LS, MG, MR, NM, OP, OT, PR, PT, PX, REG, RF, RG, RTDOSE, RTIMAGE, RTPLAN, RTRECORD, RWV, SM, SMR, SR, ST, TG, US, XA, XC)	*US*
User option	Scheduled Station AE Title		*ZONARE*
User option	Polling Interval (Minutes)	Selections: (1, 3, **5**, 10, 15, 30, 60, Disabled)	*5*
User option	Maximum Entries Cached		*200*

MPPS (*Modality Performed Procedure Step* - DICOM$_{by\ Merge}$) Setup Parameters (if applicable)

Level	Parameter Name	User Site Value/Setting	Default / Special Info
Required	MPPS Manager Nickname		
Required	MPPS Manager AE Title		
Required	IP Address (MPPS Device)		
Required	Port Number		*104*
User option	Max PDU Receive Size		*16384*
User option	Max PDU Send Size		*16384*

ARCHIVE - Print/Store Buttons Configuration:



To configure “NETWORK” parameters

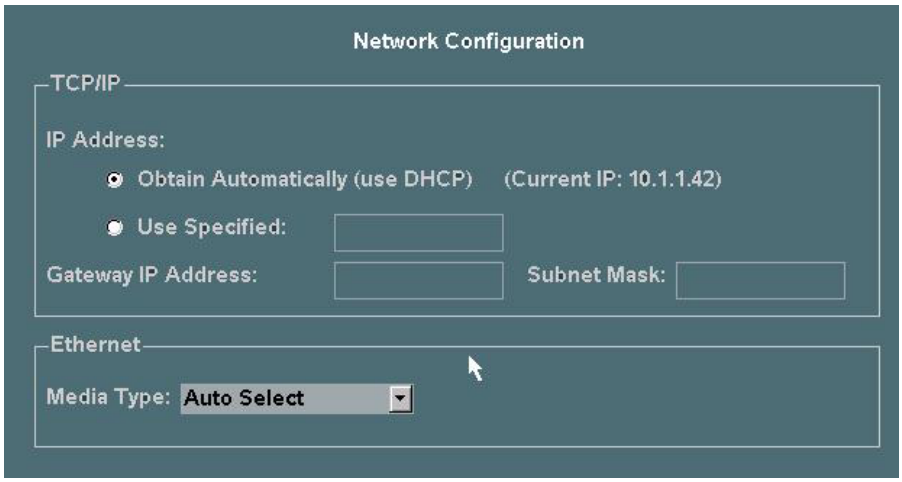


Figure 8-3. **NETWORK Configuration Screen**

1. To access the **Network Configuration screen**, select **Tools | System Setup | Network**.
2. To complete the data fields, refer to the table in section “DICOM Configuration Parameters” on page 8-3. Use the **Tab** key to advance to the next data field.
3. To save and exit, select **Apply** from the main menu to save the configuration and return to the **DICOM** menu.

To configure “GENERAL” DICOM parameters

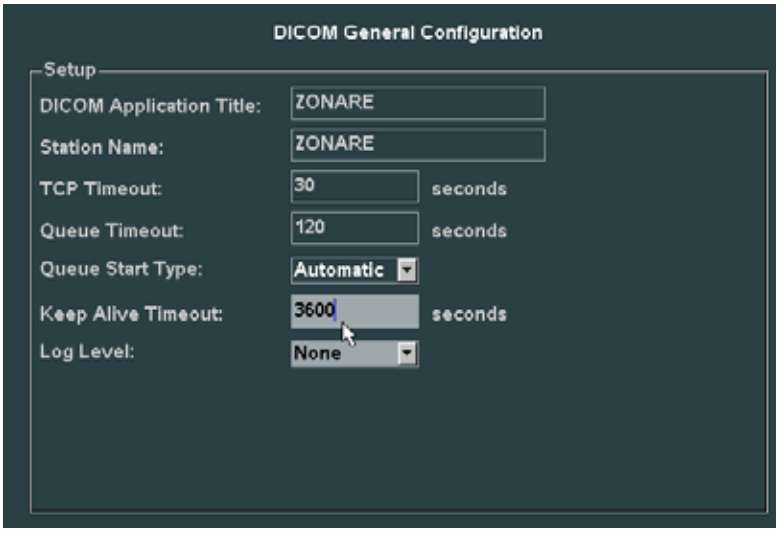


Figure 8-4. **DICOM General Configuration Screen**

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To view the **DICOM General Configuration screen**, select **Tools | System Setup | DICOM | General**.

3. To complete the data fields, refer to the table in section “DICOM Configuration Parameters” on page 8-3. Use the **Tab** key to advance to the next data field.

4. To save and exit, select **Apply** from the main menu to save the configuration and return to the **DICOM** menu.

To configure a DICOM “Network Store” device

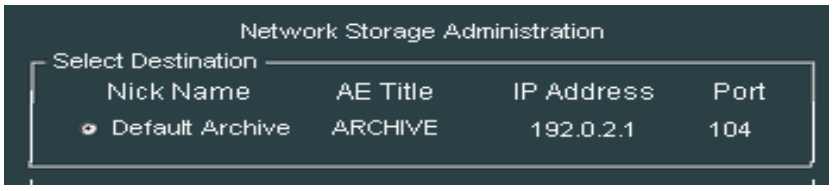


Figure 8-5. **DICOM Network Storage Administration Screen**

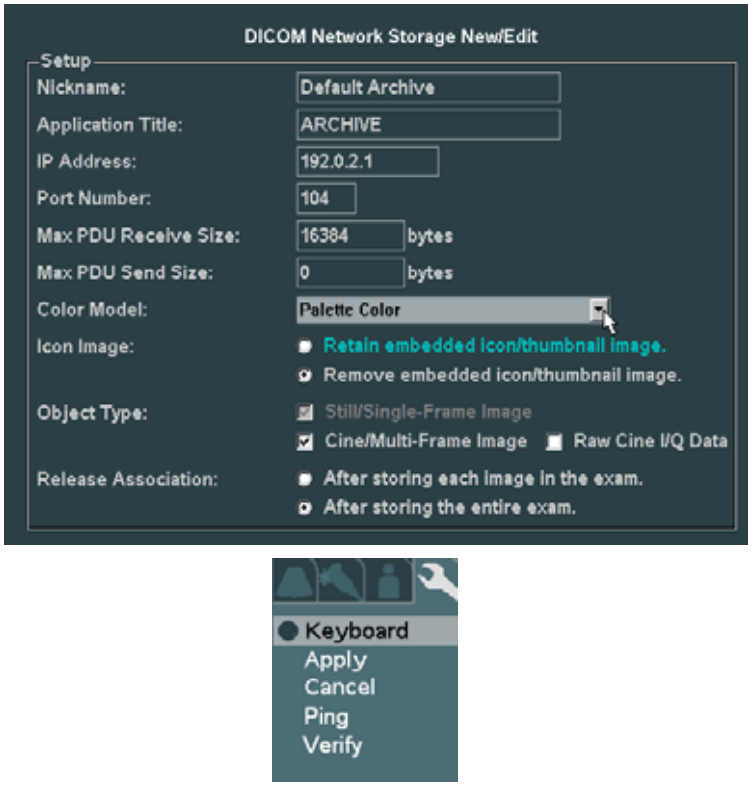


Figure 8-6. **DICOM Network Storage New/Edit Screen**

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To view the **DICOM Network Storage New / Edit screen** do the following:

   Select **Tools | System Setup | DICOM | Network Store** to view the Network Storage Administration screen (Figure 8-5). Select **New** from the main menu. Refer to Figure 8-6.

3. To complete the data fields, refer to the table in section "DICOM Configuration Parameters" on page 8-3. Use the **Tab** key to advance to the next data field.

4. To check the connection, do the following:

   – Select **Apply** from the main menu to save the configuration and return to the Network Storage Administration screen.

   – Select **Ping** from the main menu.

   If the low-level network connection has been made, the following message pops up:

ICMP Echo: xx.xx.xx.xx is alive *(xx.xx.xx.xx is the IP address of the configured device)*

– Select **Verify** from the main menu.

If the DICOM-level connection has been made, the following message pops up:

Verification of communication succeeded

If the connection has not been made, the following message pops up: Connection failure. In this case, repeat this procedure from step 1.

5. To save and exit, press **Back** to return to live imaging.

To configure the MPPS *(Modality Performed Procedure Step)*

The setup of the MPPS *(Modality Performed Procedure Step)* Manager can be configured using this procedure. Consult a network administrator to obtain all IP and DICOM parameters specific to the network on which the **Z.ONE** is connected.

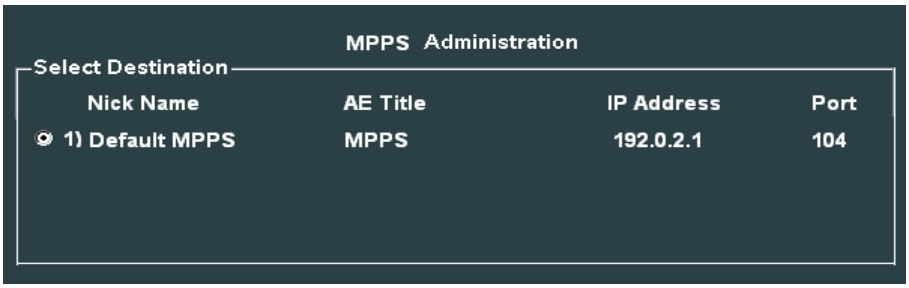


Figure 8-7. **DICOM MPPS Administration Screen**

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To view the **DICOM MPPS New / Edit screen**, do the following:

   Select **Tools | System Setup | DICOM** | **MPPS** to view the **MPPS Administration** screen (Figure 8-7). Select **New** from the main menu. Refer to Figure 8-8.

3. To complete the data fields, refer to the table in section "DICOM Configuration Parameters" on page 8-3. Use the **Tab** key to advance to the next data field.

4. To check the connection, do the following:
   – Select **Apply** from the main menu to save the configuration and return to the **MPPS Administration** screen.
   – Select **Verify** from the main menu.

   If the connection has been made, the following message pops up: *Success. Connection verified.*

   If the connection has not been made, the following message pops up: *Connection failure*. In this case, repeat this procedure from step 1.

5. To save and exit, press **Back** to return to live imaging.

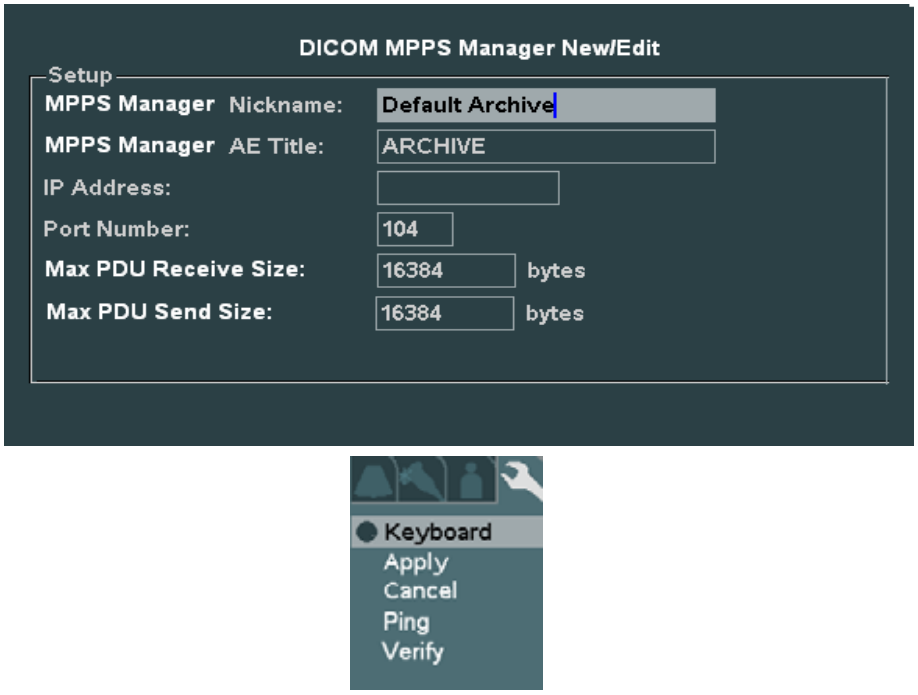


Figure 8-8. **DICOM MPPS Manager New/Edit Screen**

To configure a DICOM "Printer" device

Only DICOM-compliant printers can be configured using this procedure. Consult a network administrator to determine if the printer of interest is DICOM-compliant.

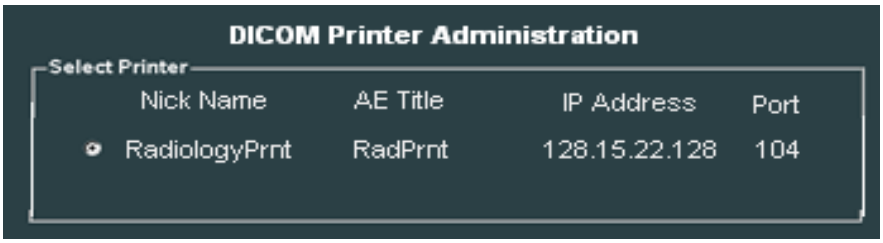


Figure 8-9. **DICOM Printer Administration Screen**

Figure 8-10. **Printer New/Edit Screen**

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To view the **DICOM Printers New / Edit screen**, do the following:

   Select **Tools | System Setup | DICOM | Printers** to view the Network Storage Administration screen (Figure 8-9). Select **New** from the main menu. Refer to Figure 8-10.

3. To complete the data fields, refer to the table in section "DICOM Configuration Parameters" on page 8-3. Use the **Tab** key to advance to the next data field.

4. To check the connection, do the following:
   – Select **Apply** from the main menu to save the configuration and return to the Network Storage Administration screen.

   – Select **Ping** from the main menu.

   If the low-level network connection has been made, the following message pops up:

   ICMP Echo: xx.xx.xx.xx is alive *(xx.xx.xx.xx is the IP address of the configured device)*

   – Select **Verify** from the main menu.

   If the DICOM-level connection has been made, the following message pops up:

   Verification of communication succeeded

   If the connection has not been made, the following message pops up: Connection failure. In this case, repeat this procedure from step 1.

5. To save and exit, press **Back** to return to live imaging.

To configure the Worklist

Figure 8-11. **DICOM Worklist Configuration**

If a DICOM worklist application is installed on the network, a list of scheduled exams can be delivered to the **z.one** on demand.

Only one Worklist application can be configured.

The list can be configured to specify a date range and other criteria for the worklist.

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To check the connection, do the following:
   - Select **Apply** from the main menu to save the configuration and return to the Network Storage Administration screen.
   - Select **Ping** from the main menu.

If the low-level network connection has been made, the following message pops up:
Success. Connection verified.

– Select **Verify** from the main menu.

If the DICOM-level connection has been made, the following message pops up:
Success. Connection verified.

3. To view the DICOM Worklist Configuration screen**,** select **Tools | System Setup | DICOM** | **Worklist** (Figure 8-11).

4. To complete the data fields, refer to the table in section "DICOM Configuration Parameters" on page 8-3. Use the **Tab** key to advance to the next data field.

5. To save and exit, select **Apply** from the main menu to save the configuration and return to live imaging.

To configure the Store and Print button functions

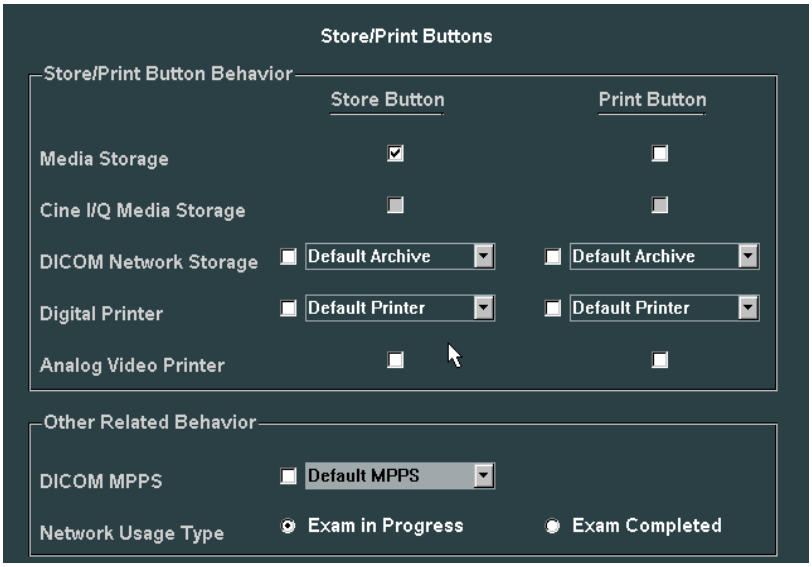


Figure 8-12. **DICOM Print/Store Buttons Configuration Screen**

1. To verify that the **z.one** is connected to the Ethernet (when the connection is live), ensure that the network icon (in the lower right-hand corner of the main imaging screen) is active (no X).

2. To view the DICOM Print/Store Buttons configuration screen, select **Tools | System Setup | Archive | Print/Store** (Figure 8-12).

3. To configure the **Store** button, to be used for triggering the remote (DICOM) **storage** of images, do the following:

   Place the arrow over the radio button to the left of the desired entry, then press **Set** to check the box. This will select that function for active use.

   Place the cursor over the drop-down menu arrow in the **DICOM Network Storage** row, for the **Store** Button selection. Press Set to open the list of all configured archive devices. Highlight the preferred device. The nickname of the selected device displays in the data field.

4. To configure the **Store** button, to be used for triggering **printing** of images, do the following:

   Place the cursor over the radio button to the left of the desired entry, then press **Set** to check the box. This will select that function for active use

   Place the cursor over the drop-down menu arrow in the **Digital Printer** row, for the **Store Button** selection. Press **Set** to open the selection list of all configured printers. Printing options consist of remote printing (via a network connection) to a DICOM printer device, or locally to a digital graphics printer (Sony UP-D897).

   On systems equipped with a video printer option and/or printing to a locally attached video printer device (Sony UP-897MD or UP-21MD), printing is configured by checking the radio box next to the **Analog Video Printer** option in the menu. Selecting **Analog Video Printer** will cause the **Z.ONE** to produce a remote trigger signal (via a cable connection) to the Sony video printer device, each time the ***STORE*** key on the SuperCart is depressed.

   Highlight the preferred device. The nickname of the selected print device displays in the data field.

5. To configure the **Store** button, to be used for triggering local (internal CompactFlash) storage of images, do the following:

   Move the cursor to radio button, for the Store Button function, in the **Media Storage** row, then press **Set** to check the box to activate this function.

6. To save and exit, select **Apply** from the main menu to save the new configuration and return to the **DICOM** menu.

7. To configure the **Print** key, to be used for triggering remote (DICOM) **storage** of images, do the following:

   Place the cursor over the radio button to the left of the desired entry, then press Set to check the box. This will select that function for active use

   Place the cursor over the drop-down menu arrow in the Network Storage row, for the **Print Button** selection. Press **Set** to open the list of all configured archive devices. Highlight the preferred device. The nickname of the selected device displays in the data field.

8. To configure the **Print** key, to be used for triggering local video **printing** of images, do the following:

   Place the cursor over the drop-down menu arrow in the **Digital Printer** row, for the **Store Button** selection. Press **Set** to open the selection list of all configured printers. Printing options consist of remote printing (via a network connection) to a DICOM printer device, or locally using a digital graphics printer (Sony UP-D897).

   On systems equipped with a video printer option and / or printing to a locally attached video printer device (Sony UP-897MD or UP-21MD), printing is configured by checking the radio box next to the **Analog Video Printer** option in the menu. Selecting **Analog Video Printer** will cause the **Z.ONE** to produce a remote trigger signal (via a cable connection) to the Sony video printer device, each time the ***STORE*** key on the SuperCart is depressed.

   Highlight the preferred device, then press **Set**. The Nickname of the selected device displays in the data field.

9. To configure the **Print** key, to be used for triggering local (internal CompactFlash) **storage** of images, do the following:

   Move the cursor to radio button, for the Print Button function, in the Media Storage row, then press **Set** to check the box to activate this function.

10. To save and exit, select **Apply** from the main menu to save the new configuration and return to the **DICOM** menu.

To configure DICOM network store image Queuing

1. To access the DICOM Print/Store Buttons configuration screen, select **Tools | System Setup | Archive | Print/Store** (Figure 8-12).

2. To configure the timing for transferring images out to the DICOM Queue for transfer (store) to the DICOM network store device, do the following:

   Within the **Other DICOM Related Behavior** window, move the cursor to the radio button for the desired method of triggering network image

transfers, then press Set to check the box of the desired operation. The selections available are:

– **Exam in Progress** (sends each image to Queue @ press of STORE)

– **Exam Completed** (sends all images saved, upon “End of Exam”)

To check or edit a DICOM configuration

1. To view the **Configuration** menu, select **Tools | System Setup | DICOM**.

2. To select the menu item for the device of interest, do the following:

   Select **Network Storage**, **Printer**, **MPPS** or **Worklist**. This displays the required configuration screen.

   In the case of a printer, view the appropriate Printer New / Edit dialog box.

3. Verify that the information entered is correct.

4. When making any required changes, ZONARE recommends that the department staff collaborate with a network administrator to edit a DICOM configuration.

5. To save and exit, do the following:

   If no changes are required, click **Cancel**.

   Select **Apply** from the main menu to save the changes and return to the **Configuration** menu.

9 Safety

Introduction

This chapter contains regulatory information, medical ultrasound safety, symbols, and product labeling information.

Symbols

The following alert symbols are used in this manual:

Draws attention to information that may relate to safety of the patient, the operator, or the equipment.

Indicates that the equipment *is not* category AP, and therefore must not be used in the presence of flammable liquids or gasses.

Indicates that the equipment on which it appears is intended for defibrillator-proof direct cardiac application (type CF), and includes circuitry to limit the patient leakage current to the levels specified in UL 2601-1, IEC 60601-1, and JIS-T-1001.

Refers to a type BF patient-applied part (B= body, F= floating applied part).

Indicates the equipment does not use a floating double insulated isolation connection, and therefore must not be connected to external equipment that is not protectively earthed (DO NOT connect to class II equipment).

Non-ionizing radiation may be produced by this device.

Storage temperature conditions

Alternating current (AC)

Direct current (DC)

Date of manufacture

Caution: Hot surface

Caution: ESD sensitive

Regulatory Information

United States Federal Law restricts this device to sale by or on the order of a physician, licensed by the law of the jurisdiction in which they practice, to use or order the use of this device. Only qualified personnel should perform ultrasound scanning of human subjects for medical diagnostics Although there have been no confirmed adverse effects of diagnostic levels of ultrasound, avoid unnecessary exposure.

The **z.one** meets the acoustic output emission guidelines established by the U.S. Food and Drug Administration (FDA). Acoustic output quantities have been measured, and are displayed, in accordance with the standards listed under “Guidance Documents”.

Device Classification

- FDA class II
- CE / MDD class IIa–rule 10 active device intended for diagnosis.

Safety Standards

All ZONARE instruments, cables, and diagnostic ultrasound imaging transducers have been designed to meet the essential requirements contained in 93 / 42 / EEC (Medical Device Directive), and all appropriate requirements contained within UL 2601-1 (Standard for Medical Electrical Equipment Part 1: General Requirements for Safety), IEC 60601- (Medical Electrical Equipment Part 1: General Requirements for Safety), and JIS-T-1001 (General Requirements of Medical Electrical Equipment), including limits for current leakage and isolation from a primary power line. Testing for compliance with the essential requirements of the Medical Device Directive has been performed.

Warnings and Cautions

It is not possible for ZONARE to anticipate every condition and situation in which the **z.one** will be used. The following warnings and cautions represent typical situations that require special attention. User knowledge and experience with a specific application and environment must also be taken into consideration in order to help ensure the safety of personnel and equipment.

Warnings - Overall Products

To achieve proper grounding reliability, the **z.one** power plug must be fully inserted into a receptacle marked “hospital grade”. Do not remove the grounding wire. If there is any question of power outlet or power cord integrity, do not proceed. Obtain qualified assistance.

To maintain proper grounding reliability, ONLY connect all ZONARE-approved (AC powered) peripheral devices (printers, etc.) that are used with the **z.one** AC power cords ONLY to the accessory outlet box (located inside the access door) at the rear of the SuperCart.

The **z.one** contains no operator-serviceable components within the enclosures. To avoid electrical shock, **do not remove covers**. As with any other electrical equipment, always observe care when operating this instrument. For service issues, contact Tech Support. Refer to “Contact Information for ZONARE Service and Technical Support” on page 11-1. Failure to follow this restrictions may void your warranty or service contract coverage. To reduce the risk of electric shock, DO NOT connect the **z.one** input or output connections to equipment that is not properly connected to an Earth ground.

The **z.one** represents a potential explosion hazard if it is used in the presence of flammable anesthetics. Use only transducers that are specifically approved for the **z.one**. If the proper identification of a connected transducer is not displayed on screen, do not proceed with its use. Inspect the transducer and Scan Engine before each use. Inspect the transducer face, housing, cable, connectors, and cases. Do not use the unit if damage is detected.

To avoid electrical shock, always unplug the SuperCart (or *mini*Cart) AC power cord from wall outlet before cleaning any part of the **z.one**. Do not immerse the transducer past the specified cleaning / disinfection level, as specified in the Transducer Care section of Chapter 10 (User Maintenance) of this manual. Do not immerse the transducer for longer than the specified cleaning / disinfecting time. Do not use any transducer that has been immersed beyond the maximum limit or has been soaked longer than the maximum specified time. The transducer must be removed from patient contact before application of a high-voltage defibrillation.

To avoid electrical shock, do not touch the battery contact. The transducer connector may reach temperatures that exceed IEC 60601-1 limits for patient contact; therefore, only the operator should handle the **z.one**. This does not include the transducer face. Patient contact with surfaces that exceed the IEC 60601-1 limit may result in discomfort or minor risk of patient injury.

The **z.one** is not intended for use in conjunction with high frequency (HF) surgical equipment (tissue ablation devices). Do not use transducers connected to the **z.one** on patients while HF surgical devices are in use.

Use only ZONARE-recommended peripherals and accessories. Use of non-specified peripherals and accessories could result in risk of electrical shock or

injury. See “SuperCart Peripherals” on page 1-19 for a listing of the recommended peripherals and accessories.

Warnings - miniCart Specific

The *mini*Cart is equipped with a Potential Equalization (PEQ) terminal. Only IEC 60601 compliant equipment is allowed to be connected to this terminal on the *mini*Cart.

If using IEC 60601 compliant equipment, that was not provided by Zonare, it is required that total leakage currents be tested and validated to be below the IEC 60601 limits.

Battery Warnings

- The battery has a safe-smart device.
- Do not disassemble or alter the battery.
- Charge the battery at room temperature.
- Do not short-circuit the battery by directly connecting the positive and negative terminals with metal objects.
- Do not heat or discard the battery in a fire.
- Do not expose the battery to temperatures above 150°F.
- Do not charge the battery near a heat source.
- Do not leave the battery in direct sunlight.
- The battery should only be charged within the Scan Engine of the **z.one**, or a ZONARE provided battery charger.
- Do not use a damaged battery.
- Inspect the battery for damage before charging or placing the battery in the **z.one**.
- Do not connect battery to an electrical power outlet.
- Do not continue to recharge the battery if it does not recharge fully after 4 hours

Cautions

Excessive bending or twisting of transducer cables may cause failure or intermittent operation of the system. Improper cleaning or sterilization of

patient applied parts may cause permanent damage. Refer to "User Maintenance" on page 10-1 regarding care and cleaning of your system.

Do not use solvents or abrasive cleaners on the SuperCart, *mini*Cart, Scan Engine, transducers, or peripheral devices.

An internal isolation transformer protects the SuperCart from excessive leakage current. In such a situation, the transformer continues to operate in standby mode. Ensure that the circuit breaker is off when before unplugging the system from the wall outlet.

Use of peripheral devices not supplied by ZONARE could result in electrical shock. When an additional peripheral device is connected to the **z.one**, ensure that the total system earth leakage current does not exceed 300 µA.

If the **z.one** will be stored in a location where power cannot be supplied (to maintain the battery in a charged state) for more than five days, remove the battery from the Scan Engine to help prevent potentially hazardous conditions as a result of the battery deteriorating.

Be aware of the potential hazards associated with the environment where the **z.one** will be used. The **z.one** and / or the external equipment can be damaged if signal levels are not appropriate. If peripheral equipment not specifically authorized by ZONARE is to be connected to the **z.one**, it must meet all applicable electrical safety standards that apply to the **z.one** in order to maintain the **z.one**'s safety integrity. Any equipment not supplied by ZONARE must be approved by ZONARE. Use of non ZONARE-approved equipment may result in an unsafe condition, impair **z.one** operation, impair diagnostic capabilities, and void your warranty or service contract coverage.

If a transducer that has not been approved for use with the **z.one** is connected, or if an approved transducer is not properly connected, the corresponding transducer identification data will not display on the LCD display. Imaging will be disabled. Resolve this issue before continuing use. The **z.one** and / or the transducer could be damaged if a nonapproved transducer is connected.

Some components or devices such as transducer covers used with the **z.one** are for single-patient use only. Reuse, reprocessing, or re-sterilization of these devices may compromise their structural integrity and lead to device failure, which, in turn, may result in patient injury, illness, or death.

Carefully review to the manufacturer's directions for any component used with the **z.one**. ZONARE Medical Systems, Inc. assumes no liability with respect to single-use devices that are reused, reprocessed, or re-sterilized and makes no warranties, expressed or implied (including the warranties of merchantability or fitness for a particular use), with respect to such devices. Improper setting of imaging controls may obscure diagnostically valuable information in the display. The factory default preset maps were preselected as appropriate for most imaging circumstances. Improper user configuration of custom presets may obscure diagnostically valuable information.

The **z.one** was manufactured in compliance with existing electromagnetic interference (EMI) and electromechanical compliance (EMC) requirements. Use of this **z.one** in the presence of an electrical magnetic field can cause degradation of the ultrasound image.

Electrostatic discharge (ESD), or static shock, is a naturally occurring phenomenon. ESD is common in low humidity, which can be caused by heating or air conditioning. ESD shock occurs when electrical energy is discharged from one body, to a less or non-charged body. To lessen the occurrence of ESD, use antistatic spray on carpets and flooring, and antistatic mats.

- If the Scan Engine has been moved between environments with extremes of temperature and / or humidity, allow the Scan Engine to rest for at least 30 minutes in a controlled environment before using.
- Do not use the **z.one** if any error message displays on the screen.

- Do not block airflow to any ventilation holes in the **z.one**.
- Do not excessively twist or bend the cables; this may cause failure.
- Follow cleaning and disinfection instructions.
- Improper cleaning or disinfection of any part of the **z.one** may cause permanent damage.
- Do not submerge the transducer past the indicated point.
- Do not use solvents or abrasives to clean any part of the **z.one**.
- Do not spill liquid on the **z.one**.

Battery Cautions

- Remove the battery from the Scan Engine during shipping or extended transport.
- Do not immerse the battery in water or allow it to get wet.
- Do not put the battery into a microwave oven or pressurized container.
- Use only ZONARE supplied batteries.
- Store the battery between 32° and 120°F (0° and 50°C).
- If the battery leaks, emits odor or heat, is deformed or discolored in any way immediately remove it and stop using it.

Precautions

The **z.one** has been designed to comply with the IEC 60601-1-2, Electromagnetic Compatibility standard. Operating the **z.one** in the presence of external electromagnetic fields can degrade the quality of the ultrasound image. Portable and mobile communication equipment, such as two-way radios, can produce image artifacts. If required, a review of the local electromagnet environment may be required to minimize the sources of external noise generators.

The use of non-ZONARE approved cables and accessories may result in increased EMI emissions as well as decreased immunity to external signal fields.

Prior to beginning to image a new patient, be sure to conclude any in-progress patient exam, by pressing the **New Patient** key (on the SuperCart or *mini*Cart) or the **New** selection from the **Patient** tab on the Scan Engine. Failure to do so will result in any subsequent storing of images being mistakenly written to the previous patient exam directory.

Exercise care in adjusting all settings to avoid obscuring low-level signals that may have diagnostic value. Improper settings can seriously degrade image quality.

Fold down the SuperCart (or *mini*Cart) LCD display, into its latched storage position, when not in use. Connect the SuperCart (or *mini*Cart) to an active power receptacle to maintain the batteries in a charged condition. Any image sets stored on in the **z.one** that are not identified by patient name and number will be deleted when a new exam is started.

Validate all entries in the Measurement Summary.

Electrical Safety

The **z.one** meets IEC 60601-1, Class I powered equipment requirements, and Type BF isolated patient-applied parts (transducers) safety requirements.

The ZONARE Ultrasound **z.one** complies with the applicable medical equipment requirements published in the European Norm Harmonized Standards.

The transducers and **z.one** are certified to be in compliance with IEC 60601-1, and limit the enclosure leakage currents to nonpatient connected levels in both normal and single-fault conditions. The system's earth enclosure, and patient leakage current, is tested during production on all systems for primary power and ground conductor faults.

Medical Ultrasound Safety

Anyone using the **z.one** for human exams of any kind should thoroughly understand the implications of such use. The American Institute of Ultrasound in Medicine (AIUM) has published a document titled *Medical Ultrasound Safety* (AIUM 1994). ALARA is an abbreviation for the principle of prudent use of diagnostic ultrasound by obtaining the diagnostic information at a power output that is "As Low As Reasonably Achievable."

A copy of this AIUM document, addressing ALARA principles, is provided with each **z.one**.

Acoustic Output

This section describes acoustic output related parameters and considers the relation between these parameters and user controls on the ZONARE **z.one**. The display accuracy and measurements precision of these parameters is also discussed.

Detailed information on acoustical power output for each transducer, in each operating modality, is provided in the dedicated tables beginning with Table 9-13.

Acoustical power output is dependent on both system control settings and the probe selected.

ALARA Principle

The prudent use of ultrasound requires a constant consideration of the risk-benefit ratio for the patient, along with employment of the ALARA principle. ALARA stands for "**A**s **L**ow **A**s **R**easonably **A**chievable." ALARA means that the sonographer uses only a much ultrasonic power for as long as needed to obtain the necessary clinical information. With training, education, and experience, the sonographer can systematically keep the patient risk for potential bioeffects of ultrasound to a minimum. ALARA is the guiding principle for the use of diagnostic ultrasound. Qualified sonographers, using good judgment and insight, determine the exposure that is as low as reasonably achievable. There are no rules to determine the correct response to every situation. The sonographer keeps exposure low, bioeffects minimal, and images diagnostic. A thorough knowledge of the imaging modes, probes, system, and scanning techniques for this system is necessary.

The acoustic output of this device has been measured and calculated per the "Acoustic Output Measurement Standard for Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" (NEMA, UD 2), and the "Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2" (NEMA UD3).

Applying ALARA

The scanner-imaging mode is selected by the sonographer and is determined by what information is required, For example, 2D imaging provides anatomical information. Understanding the nature of the imaging mode being used allows a trained sonographer to apply the ALARA principle.

With training, education, and experience, the sonographer can systematically keep the patient risks for potential bioeffects of ultrasound down to a minimum. This means using ultrasound as an effective and often essential source of diagnostic information and not as a source of entertainment.

For information about ALARA and possible bioeffects, refer to the Medical Ultrasound Safety brochure developed by the American Institute of Ultrasound in Medicine (AIUM) and supplied with the **z.one**.

Direct Controls

The **z.one** controls acoustic output to not exceed a mechanical index (MI) level of 1.9, an $I_{SPTA.3}$ of 720 mW / cm^2 or a thermal index (TI) value of 6.0.

The **z.one**'s factory-set defaults, which are user adjustable, are such that when changing from one preset to another, one transducer to another, or a non-fetal to a fetal application, the **z.one** selects default MI & $I_{SPTA.3}$ values that are significantly lower than FDA limits.

The thermal index that is displayed (TIS, TIB, TIC) is based on the selected application.

The system acoustic output display and controls follow the "*Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2"* (NEMA UD3).

Indirect Controls

The controls that indirectly affect output are controls affecting the imaging mode, optimization, probe selection, and depth. The imaging mode determines the nature of the ultrasound beam. Tissue attenuation is directly related to transducer frequency. The higher the pulse repetition frequency (PRF), the more output pulses occur over a period of time. Refer to Table 8-3, "Measurement Acoustic Value Accuracy" on page 9-48.

Receiver Controls

The receiver controls (such as **Gain, Dynamic Range,** etc.) do not affect acoustic output. Use the receiver controls to improve the image quality before using controls that directly or indirectly affect output.

General Controls

Transducer

Each ZONARE transducer has different physical characteristic and acoustic response to transmit voltages. Differences include size and shape, center frequency, piezo-electric efficiency, and focus properties of the lens. Changing from one transducer model to another will change the acoustic output and therefore the displayed mechanical index and thermal index values.

Mode

Changing from one mode to another will affect the acoustic output. Different modes use different transmit waveforms, focusing, duty cycles, and pulsing sequences. Doppler modes tend to have higher duty cycles, and therefore higher TI values, than B and M modes. Modes using the tightest focusing will tend to have higher MI values.

Defaults

Default settings exist and are accessed whenever a transducer and mode combination is selected. Although the acoustic output associated with these defaults may differ from combination to combination, the default acoustic output is lower than the FDA limits.

Transmit Power

Transmit power controls the transmit voltage, and therefore the amplitude of the transmitted ultrasonic waves. Both the TI and the MI will change when Transmit power (**A Output**) is adjusted.

*Automatic **z.one** Limiting*

For any adjustment described in the mode-specific section below, when a user adjustment of a **z.one** control causes the MI, TI or any other acoustic output or surface-temperature related parameter to reach a **z.one** control limit, the **z.one** will automatically decrease the transmit voltage, causing a decrease in one or more of those parameters.

B-Mode Controls

Image Width

Narrowing the image width may increase the frame rate, which may increase the TI.

Depth

Decreasing the depth may increase the frame rate, which may increase the TI.

Operating Frequency

Changing the operating frequency will affect the displayed MI and TI values as the beam formation is affected and transducer efficiencies may differ between frequencies.

Frame Rate

A lower frame rate may decrease the TI, however due to an increase in the Image Width, the TI stays roughly constant, if the **z.one**^{s} transmit pulse repetition stays constant.

Zoom

Increasing or decreasing the zoom may affect the frame rate, which may increase or decrease the TI.

Image Presets

Changing the image presets may indirectly change the acoustic line spacing or the frame rate, which could change the TI values. An increasing spacing may decrease the TI, and an increasing frame rate may increase the TI.

Color Doppler Controls

Velocity Scale

Increasing the Velocity scale may increase the TI by increasing the **z.one** pulse repetition frequency.

Color ROI Size and Position

A narrower Color Region Of Interest (ROI) may increase the frame rate, which may increase the TI. A longer Color ROI, or a deeper Color ROI, may decrease the **z.one** pulse repetition frequency and decrease the TI.

Operating Frequency

Changing the operating frequency will affect both the displayed MI and TI values because the beam formation is affected and transducer efficiencies may differ between frequencies.

Combinational with B-Mode

Use of combination modes affects the TI and the MI through the combination of pulse types. Because the TI is additive, simultaneous pulsing of B and COLOR modes will cause larger TI values than sequential pulsing (e.g., auto-update). The displayed MI will be from the pulses with the largest peak pressure.

Image Presets

Changing the image presets may indirectly change the color sensitivity. Increasing the sensitivity could increase the TI values.

Transducers: Performance (Measured)

The information in the following tables describes the measured performance characteristics of each of the transducers currently offered for use on the **z.one.**

Table 9-1. **C5-2 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	24.0 CM
Resolution (Axial)	0.45 mm
Resolution (Lateral)	1.40 mm
Ultrasound Frequency	3.525 MHz
Ultrasound Bandwidth	1.31 MHz
Highest Observed Surface Temp	41.9 degrees (C)

Table 9-2. **E9-4 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	11.5 CM
Resolution (Axial)	0.35 mm
Resolution (Lateral)	0.83 mm
Ultrasound Frequency	6.775 MHz
Ultrasound Bandwidth	2.355 MHz
Highest Observed Surface Temp	41.5 degrees (C)

Table 9-3. **L10-5 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	10.0 CM
Resolution (Axial)	0.30 mm
Resolution (Lateral)	0.40 mm
Ultrasound Frequency	6.48 MHz
Ultrasound Bandwidth	3.47 MHz
Highest Observed Surface Temp	42.3 degrees (C)

Table 9-4. **P4-1 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	30 CM
Resolution (Axial)	0.4 mm
Resolution (Lateral)	1.8 mm
Ultrasound Frequency	3.48 MHz
Ultrasound Bandwidth	1.48 MHz
Highest Observed Surface Temp	42.1 degrees (C)

Table 9-5. **P10-4 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	12 CM
Resolution (Axial)	0.3 mm
Resolution (Lateral)	0.8 mm
Ultrasound Frequency	7.23 MHz
Ultrasound Bandwidth	2.73 MHz
Highest Observed Surface Temp	41.7 degrees (C)

Table 9-6. **L8-3 Transducer: Measured Results**

Measured Item	Measured Result
Penetration Depth	10 CM
Resolution (Axial)	0.2 mm
Resolution (Lateral)	0.5 mm
Ultrasound Frequency	6.33 MHz
Ultrasound Bandwidth	3.32 MHz
Highest Observed Surface Temp	42.1 degrees (C)

Transducers: Acoustic Power Output

Acoustical power output varies among different models of probes. Specific acoustic power output values for each transducer, for each mode of operation, are provided in tables beginning with Table 9-8.

The defaults of each probe / mode combination will be set such that the acoustic output will be less than either 3 dB below the maximum acoustic output for the operating condition or 6 dB below FDA limits. 6 dB equates to 50% of the FDA limit for MI, and 25% of the limit for Ispta.3 and TI.

The tables on the following pages specify the Track3 reporting values, in each operating modality, for each **z.one** transducer.

Table 9-7. **Terminology for Acoustic Reporting Table for Track 3**

Term	Definition	Units
MI	Mechanical Index	
TISscan	Soft Tissue Thermal Index in an auto-scanning mode	
TISnon-scan	Soft Tissue Thermal Index in the non auto-scanning mode	
TIB	Bone Thermal Index	
TIC	Cranial Thermal Index	
Aaprt	Area of the active aperture measured	cm^2
Pr.3	Derated peak rarefactional pressure	MPa
Wo	Ultrasonic power, except for TIScan. Wo with reference to TISscan is the ultrasonic power passing through the central 1cm length of the transducer with the highest linear power density.	mW
W.3(z1)	Derated ultrasonic power at axial distance z1.	mW
Ita.3(z1)	Derated spatial peak, temporal average intensity at axial distance z1	mW/cm^2
z1	Axial distance corresponding to the location of maximum [min (W.3 (z), Ita.3 (z) x 1 cm^2)], where z >= zbp	cm
zbp	$1.69\sqrt{A_{aprt}}$	cm

Table 9-7. **Terminology for Acoustic Reporting Table for Track 3**

Term	Definition	Units
zsp	For MI, zsp is the axial distance at which pr.3 is measured. For TIB, zsp is the axial distance at which TIB is a maximum (zsp = zb.3).	cm
deq(z)	Equivalent beam diameter as a function of axial distance z, and is equal to p[(4/p) (Wo/ITA(z))], where ITA(z) is the temporal average intensity as a function of z	cm
Fc	Center frequency	MHz
Dim. of Aaprt	Active aperture dimensions for the azimuthal (x) and elevational (y) planes	cm
PD	Pulse duration	μS
PRF	Pulse repetition frequency	Hz
$Pr@PII_{max}$	Peak rarefactional pressure at the point where the free-field, spatial peak pulse intensity integral is a maximum	MPa
FL	Focal length, or azimuthal (x) and elevational (y) lengths, if different	cm
deq@PIImax	Equivalent beam diameter at the point where the free-field, spatial peak pulse intensity integral is a maximum	cm
Ipa.3@MImax	Derated pulse average intensity at the selected operating condition of maximum MI	W/cm^2
SV	Doppler sample volume size	mm
MPa	MegaPascals	

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-8. **L8-3 Transducer - B-Mode**

Transducer Model: L8-3 Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.38	0.17	-	-	-	0.29
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.57					
	W_o	(mW)		13.93	-		-	13.93
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.65				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	3.46	3.46	-	-	-	3.46
	Dim of A_{aprt}	X (cm)		0.72	-	-	-	0.72
		Y (cm)		0.60	-	-	-	0.60
Other Information	PD	(µsec)	0.40					
	PRF	(Hz)	2465.11					
	pr@PIImax	(MPa)	3.14					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		2.80	-	-		2.80
		FL_y (cm)		2.50	-	-		2.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	335.24					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-9. **L8-3 Transducer - M-Mode**

Transducer Model: L8-3 Operating Mode: M-Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS non-scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.47	-	0.12	-	0.42	0.23
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.83					
	W_o	(mW)		-	8.24		8.24	8.24
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.65				1.88	
	$d_{eq}(z_{sp})$	(cm)					0.14	
	f_c	(MHz)	3.69	-	3.46-3.69	-	3.69	3.46-3.69
	Dim of A_{aprt}	X (cm)		-	0.72	-	0.72	0.72
		Y (cm)		-	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.47					
	PRF	(Hz)	720.07					
	pr@PIImax	(MPa)	3.42					
	deq@PIImax	(cm)					0.14	
	Focal Length	FL_x (cm)		-	2.80	-		2.80
		FL_y (cm)		-	2.50	-		2.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	418.24					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-10. **L8-3 Transducer - PW-Mode**

Transducer Model: L8-3 Operating Mode: PW Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.30	(c)	1.30	-	1.73	1.41
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.50					
	W_o	(mW)		#	60.42		60.42	60.42
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.65				2.12	
	$d_{eq}(z_{sp})$	(cm)					0.41	
	f_c	(MHz)	3.67	#	4.50	-	4.50	4.50
	Dim of A_{aprt}	X (cm)		#	1.50	-	1.50	1.50
		Y (cm)		#	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.49					
	PRF	(Hz)	97.78					
	pr@PIImax	(MPa)	3.01					
	deq@PIImax	(cm)					0.28	
	Focal Length	FL_x (cm)		#	6.00	-		6.00
		FL_y (cm)		#	2.50	-		2.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	247.57					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-11. **L8-3 Transducer - Color Mode**

Transducer Model: L8-3 Operating Mode: COLOR Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.31	(c)	0.55	-	1.07	1.08
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.43					
	W_o	(mW)		#	35.63		35.63	35.63
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.77				0.50	
	$d_{eq}(z_{sp})$	(cm)					0.50	
	f_c	(MHz)	3.46	#	3.12-3.59	-	3.59	3.12-3.59
	Dim of A_{aprt}	X (cm)		#	0.96	-	0.72	0.96
		Y (cm)		#	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.40					
	PRF	(Hz)	1260.00					
	pr@PIImax	(MPa)	2.93					
	deq@PIImax	(cm)					0.33	
	Focal Length	FL_x (cm)		#	7.0-12.0	-		7.0-12.0
		FL_y (cm)		#	2.50	-		2.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	310.58					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-12. **L8-3 Transducer - Triplex Mode**

Transducer Model: L8-3 Operating Mode: Triplex Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.31	(c)	1.30	-	1.73	1.41
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.43					
	W_o	(mW)		#	60.42		60.42	60.42
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.77				3.58	
	$d_{eq}(z_{sp})$	(cm)					0.81	
	f_c	(MHz)	2.03	#	4.50	-	2.03	4.50
	Dim of A_{aprt}	X (cm)		#	1.50	-	2.82	1.50
		Y (cm)		#	0.60	-	1.20	0.60
Other Information	PD	(µsec)	0.40					
	PRF	(Hz)	1260.00					
	pr@PIImax	(MPa)	2.93					
	deq@PIImax	(cm)					0.46	
	Focal Length	FL_x (cm)		#	6.00	-		6.00
		FL_y (cm)		#	2.50	-		2.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	310.58					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-13. **L10-5 Transducer - B-Mode**

Transducer Model: L10-5 Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.16	0.25	-	-	-	0.28
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.81					
	W_o	(mW)		12.41	-		-	12.41
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.19				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	5.94	5.94	-	-	-	5.94
	Dim of A_{aprt}	X (cm)		0.72	-	-	-	0.72
		Y (cm)		0.50	-	-	-	0.50
Other Information	PD	(µsec)	0.42					
	PRF	(Hz)	810.83					
	pr@PIImax	(MPa)	3.47					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		4.00	-	-		4.00
		FL_y (cm)		1.75	-	-		1.75
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	377.42					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-14. **L10-5 Transducer - M-Mode**

Transducer Model: L10-5 Operating Mode: M-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.25	0.06	-	0.07	0.30	0.23
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.56					
	W_o	(mW)		8.42	-		8.42	8.42
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				3.28		
	z_1	(cm)				0.85		
	z_{bp}	(cm)				0.85		
	z_{sp}	(cm)	1.19				1.19	
	$d_{eq}(z_{sp})$	(cm)					0.22	
	f_c	(MHz)	4.24	4.10-4.24	-	4.24	4.24	4.10-4.24
	Dim of A_{aprt}	X (cm)		0.96	-	0.96	0.96	0.96
		Y (cm)		0.50	-	0.50	0.50	0.50
Other Information	PD	(µsec)	0.46					
	PRF	(Hz)	720.07					
	pr@PIImax	(MPa)	2.95					
	deq@PIImax	(cm)					0.18	
	Focal Length	FL_x (cm)		3.0-4.0	-	3.0-4.0		3.0-4.0
		FL_y (cm)		1.75	-	1.75		1.75
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	230.40					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-15. **L10-5 Transducer - PW Mode**

Transducer Model: L10-5 Operating Mode: PW Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt}\leq 1$	$A_{aprt}>1$	scan	
Global Maximum Index Value			1.14	(c)	1.55	-	3.98	1.56
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.47					
	W_o	(mW)		#	68.79		68.79	68.79
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.19				0.96	
	$d_{eq}(z_{sp})$	(cm)					0.33	
	f_c	(MHz)	4.73	#	4.73	-	4.73	4.73
	Dim of A_{aprt}	X (cm)		#	1.92	-	1.92	1.92
		Y (cm)		#	0.50	-	0.50	0.50
Other Information	PD	(µsec)	0.92					
	PRF	(Hz)	966.56					
	pr@PIImax	(MPa)	2.95					
	deq@PIImax	(cm)					0.33	
	Focal Length	FL_x (cm)		#	9.00	-		9.00
		FL_y (cm)		#	1.75	-		1.75
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	325.77					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-16. **L10-5 Transducer - Color Mode**

Transducer Model: L10-5 Operating Mode: COLOR Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.21	(c)	0.42	-	0.65	0.63
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.82					
	W_o	(mW)		#	20.79		20.79	20.79
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.08				1.08	
	$d_{eq}(z_{sp})$	(cm)					0.25	
	f_c	(MHz)	5.47	#	3.90-5.47	-	5.47	3.90-5.47
	Dim of A_{aprt}	X (cm)		#	0.72	-	0.72	0.72
		Y (cm)		#	0.50	-	0.50	0.50
Other Information	PD	(µsec)	0.95					
	PRF	(Hz)	371.85					
	pr@PIImax	(MPa)	3.21					
	deq@PIImax	(cm)					0.25	
	Focal Length	FL_x (cm)		#	4.0-12.0	-		4.0-12.0
		FL_y (cm)		#	1.75	-		1.75
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	1.75					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-17. **L10-5 Transducer - Triplex Mode**

Transducer Model: L10-5 Operating Mode: Triplex Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.14	(c)	1.43	-	3.82	1.48
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.47					
	W_o	(mW)		#	64.79		64.79	64.79
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.19				0.96	
	$d_{eq}(z_{sp})$	(cm)					0.34	
	f_c	(MHz)	4.72	#	4.52-6.02	-	4.64	4.52-6.02
	Dim of A_{aprt}	X (cm)		#	1.92	-	1.92	1.92
		Y (cm)		#	0.50	-	0.50	0.50
Other Information	PD	(µsec)	0.92					
	PRF	(Hz)	966.56					
	pr@PIImax	(MPa)	2.95					
	deq@PIImax	(cm)					0.39	
	Focal Length	FL_x (cm)		#	4.0-12.0	-		4.0-12.0
		FL_y (cm)		#	1.75	-		1.75
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	332.96					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-18. **C5-2 Transducer - B-Mode**

Transducer Model: C5-2 Operating Mode: B- Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					A_{aprt}≤1	A_{aprt}>1	scan	
Global Maximum Index Value			1.07	0.19	-	-	-	0.48
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.51					
	W_o	(mW)		40.58	-		-	40.58
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	3.06				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.98	1.98	-	-	-	1.98
	Dim of A_{aprt}	X (cm)		1.06	-	-	-	1.06
		Y (cm)		1.20	-	-	-	1.20
Other Information	PD	(µsec)	1.40					
	PRF	(Hz)	1880.44					
	pr@PIImax	(MPa)	1.88					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		7.00	-	-		7.00
		FL_y (cm)		7.00	-	-		7.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	89.49					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-19. **C5-2 Transducer - M-Mode**

Transducer Model: C5-2 Operating Mode: M Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS non-scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.05	0.06	-	0.17	0.64	0.58
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.45					
	W_o	(mW)		34.29	-		34.29	34.29
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				18.98		
	z_1	(cm)				1.01		
	z_{bp}	(cm)				1.01		
	z_{sp}	(cm)	3.06				3.58	
	$d_{eq}(z_{sp})$	(cm)					0.48	
	f_c	(MHz)	1.93	1.92-1.93	-	1.92	1.92	1.92-1.93
	Dim of A_{aprt}	X (cm)		1.06	-	1.06	1.06	1.06
		Y (cm)		1.20	-	1.20	1.20	1.20
Other Information	PD	(µsec)	1.09					
	PRF	(Hz)	568.48					
	pr@PIImax	(MPa)	1.73					
	deq@PIImax	(cm)					0.47	
	Focal Length	FL_x (cm)		7.00	-	7.00		7.00
		FL_y (cm)		7.00	-	7.00		7.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	81.80					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-20. **C5-2 Transducer - PW Mode**

Transducer Model: C5-2 Operating Mode: PW Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS non-scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.07	(c)	-	1.04	3.77	2.01
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.51					
	W_o	(mW)		#	-		151.68	151.68
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				108.17		
	z_1	(cm)				2.29		
	z_{bp}	(cm)				1.01		
	z_{sp}	(cm)	3.06				6.40	
	$d_{eq}(z_{sp})$	(cm)					0.37	
	f_c	(MHz)	1.98	#	-	2.02	2.02	1.92-2.02
	Dim of A_{aprt}	X (cm)		#	-	2.33	2.33	2.33
		Y (cm)		#	-	1.20	1.20	1.20
Other Information	PD	(µsec)	1.40					
	PRF	(Hz)	1880.44					
	pr@PIImax	(MPa)	1.88					
	deq@PIImax	(cm)					0.34	
	Focal Length	FL_x (cm)		#	-	7.0-9.0		7.0-9.0
		FL_y (cm)		#	-	7.00		7.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	89.49					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-21. **C5-2 Transducer - Color Mode**

Transducer Model: C5-2 Operating Mode: COLOR Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			0.89	1.13	1.13	-	-	1.74
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.23					
	W_o	(mW)		93.07	93.07		-	93.07
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	3.06				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	1.92	1.92-2.90	1.92-2.90	-	-	1.92-2.90
	Dim of A_{aprt}	X (cm)		1.08	1.08	-	-	1.08
		Y (cm)		1.20	1.20	-	-	1.20
Other Information	PD	(µsec)	1.10					
	PRF	(Hz)	900.00					
	pr@PIImax	(MPa)	1.48					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		7.0-24.0	7.0-24.0	-		7.0-24.0
		FL_y (cm)		7.00	7.00	-		7.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	55.34					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-22. **C5-2 Transducer - Triplex Mode**

Transducer Model: C5-2 Operating Mode: Triplex Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			0.89	1.13	-	1.20	3.90	2.26
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.23					
	W_o	(mW)		93.07	-		163.43	163.43
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				104.43		
	z_1	(cm)				2.29		
	z_{bp}	(cm)				1.01		
	z_{sp}	(cm)	3.06				6.65	
	$d_{eq}(z_{sp})$	(cm)					0.36	
	f_c	(MHz)	2.03	1.92-2.90	-	2.02	2.02	1.92-2.90
	Dim of A_{aprt}	X (cm)		1.08	-	2.33	2.33	2.33
		Y (cm)		1.20	-	1.20	1.20	1.20
Other Information	PD	(µsec)	1.10					
	PRF	(Hz)	900.00					
	pr@PIImax	(MPa)	1.48					
	deq@PIImax	(cm)					0.34	
	Focal Length	FL_x (cm)		7.0-24.0	-	7.0-24.0		7.0-24.0
		FL_y (cm)		7.00	-	7.00		7.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	55.34					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-23. **E9-4 Transducer - B-Mode**

Transducer Model: E9-4 Operating Mode: B- Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.28	0.64	-	-	-	0.71
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.88					
	W_o	(mW)		29.38	-		-	29.38
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.47				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	5.07	5.07	-	-	-	5.07
	Dim of A_{aprt}	X (cm)		0.50	-	-	-	0.50
		Y (cm)		0.60	-	-	-	0.60
Other Information	PD	(µsec)	0.49					
	PRF	(Hz)	3381.39					
	pr@PIImax	(MPa)	3.59					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		3.50	-	-		3.50
		FL_y (cm)		3.50	-	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	271.47					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-24. **E9-4 Transducer - M-Mode**

Transducer Model: E9-4 Operating Mode: M- Mode

Index Label			MI	TIS scan	TIS non- $A_{aprt} \leq 1$	TIS scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.25	-	0.22	-	0.20	0.28
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.82					
	W_o	(mW)		-	9.34		9.34	9.34
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.47				1.72	
	$d_{eq}(z_{sp})$	(cm)					0.19	
	f_c	(MHz)	5.08	-	5.08-5.08	-	5.08	5.08-5.08
	Dim of A_{aprt}	X (cm)		-	0.50	-	0.50	0.50
		Y (cm)		-	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.49					
	PRF	(Hz)	720.07					
	pr@PIImax	(MPa)	3.52					
	deq@PIImax	(cm)					0.19	
	Focal Length	FL_x (cm)		-	3.50	-		3.50
		FL_y (cm)		-	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	254.40					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-25. **E9-4 Transducer - PW Mode**

Transducer Model: E9-4 Operating Mode: PW Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt}\leq 1$	TIS non-scan $A_{aprt}>1$	TIB non-scan	TIC
Global Maximum Index Value			1.41	(c)	1.11	-	2.37	1.44
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.01					
	W_o	(mW)		#	51.94		51.94	51.94
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.23				1.84	
	$d_{eq}(z_{sp})$	(cm)					0.28	
	f_c	(MHz)	4.54	#	4.50	-	4.50	4.50
	Dim of A_{aprt}	X (cm)		#	1.07	-	1.07	1.07
		Y (cm)		#	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.84					
	PRF	(Hz)	1445.69					
	pr@PIImax	(MPa)	3.51					
	deq@PIImax	(cm)					0.28	
	Focal Length	FL_x (cm)		#	6.00	-		6.00
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	355.61					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-26. **E9-4 Transducer - Color Mode**

Transducer Model: E9-4 Operating Mode: COLOR Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.25	(c)	0.66	-	0.16	0.96
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	2.82					
	W_o	(mW)		#	32.27		14.07	32.27
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.47				0.50	
	$d_{eq}(z_{sp})$	(cm)					0.55	
	f_c	(MHz)	5.07	#	4.18-5.00	-	4.18	4.18-5.00
	Dim of A_{aprt}	X (cm)		#	0.67	-	0.50	0.67
		Y (cm)		#	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.49					
	PRF	(Hz)	1140.00					
	pr@PIImax	(MPa)	3.52					
	deq@PIImax	(cm)					0.42	
	Focal Length	FL_x (cm)		#	3.5-7.0	-		3.5-7.0
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	256.94					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**;
see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-27. **E9-4 Transducer - Triplex Mode**

Transducer Model: E9-4 Operating Mode: Triplex Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt}\leq 1$	TIS non-scan $A_{aprt}>1$	TIB non-scan	TIC
Global Maximum Index Value			1.41	(c)	1.13	-	2.37	1.49
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.01					
	W_o	(mW)		#	52.88		51.94	52.88
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.23				1.84	
	$d_{eq}(z_{sp})$	(cm)					0.28	
	f_c	(MHz)	4.54	#	4.16-5.05	-	4.50	4.16-5.05
	Dim of A_{aprt}	X (cm)		#	1.07	-	1.07	1.07
		Y (cm)		#	0.60	-	0.60	0.60
Other Information	PD	(µsec)	0.84					
	PRF	(Hz)	1445.69					
	pr@PIImax	(MPa)	3.51					
	deq@PIImax	(cm)					0.28	
	Focal Length	FL_x (cm)		#	3.5-14.0	-		3.5-14.0
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	355.61					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-28. **P4-1 Transducer - B-Mode**

Transducer Model: P4-1 Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.30	0.90	-	-	-	1.33
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.85					
	W_o	(mW)		71.02	-		-	73.05
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	3.85				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	2.04	2.83	-	-	-	2.04
	Dim of A_{aprt}	X (cm)		1.06	-	-	-	1.06
		Y (cm)		1.40	-	-	-	1.40
Other Information	PD	(µsec)	0.89					
	PRF	(Hz)	1793.96					
	pr@PIImax	(MPa)	2.29					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		6.00	-	-		6.00
		FL_y (cm)		10.00	-	-		10.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	151.17					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-29. **P4-1 Transducer - M-Mode**

Transducer Model: P4-1 Operating Mode: M-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-scan		non-scan	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$		
Global Maximum Index Value			1.26	0.10	-	0.13	0.39	0.46
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.80					
	W_o	(mW)		25.39	-		25.39	25.39
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				13.60		
	z_1	(cm)				0.50		
	z_{bp}	(cm)				0.50		
	z_{sp}	(cm)	4.22				2.36	
	$d_{eq}(z_{sp})$	(cm)					0.60	
	f_c	(MHz)	2.04	2.04-2.04	-	2.04	2.04	2.04-2.04
	Dim of A_{aprt}	X (cm)		1.06	-	1.06	1.06	1.06
		Y (cm)		1.40	-	1.40	1.40	1.40
Other Information	PD	(µsec)	0.89					
	PRF	(Hz)	265.29					
	pr@PIImax	(MPa)	2.22					
	deq@PIImax	(cm)					0.46	
	Focal Length	FL_x (cm)		6.00	-	6.00		6.00
		FL_y (cm)		10.00	-	10.00		10.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	142.22					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-30. **P4-1 Transducer - PW Mode**

Transducer Model: P4-1 Operating Mode: PW Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.30	(c)	-	1.03	3.14	1.93
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.85					
	W_o	(mW)		#	-		122.50	122.50
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				86.99		
	z_1	(cm)				1.99		
	z_{bp}	(cm)				1.99		
	z_{sp}	(cm)	3.85				4.96	
	$d_{eq}(z_{sp})$	(cm)					0.37	
	f_c	(MHz)	2.04	#	-	2.49	2.49	2.49
	Dim of A_{aprt}	X (cm)		#	-	1.41	1.41	1.41
		Y (cm)		#	-	1.40	1.40	1.40
Other Information	PD	(µsec)	0.89					
	PRF	(Hz)	1793.96					
	pr@PIImax	(MPa)	2.29					
	deq@PIImax	(cm)					0.37	
	Focal Length	FL_x (cm)		#	-	6.00		6.00
		FL_y (cm)		#	-	10.00		10.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	151.17					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-31. **P4-1 Transducer - Color Mode**

Transducer Model: P4-1 Operating Mode: COLOR Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt}\leq 1$	TIS non-scan $A_{aprt}>1$	TIB non-scan	TIC
Global Maximum Index Value			1.22	(c)	1.05	-	2.34	2.24
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.75					
	W_o	(mW)		#	46.30		48.79	48.79
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	4.22				1.24	
	$d_{eq}(z_{sp})$	(cm)					0.53	
	f_c	(MHz)	2.05	#	2.05-2.89	-	2.49	1.75-2.49
	Dim of A_{aprt}	X (cm)		#	1.06	-	0.53	1.06
		Y (cm)		#	1.40	-	1.40	1.40
Other Information	PD	(µsec)	0.89					
	PRF	(Hz)	420.00					
	pr@PIImax	(MPa)	2.15					
	deq@PIImax	(cm)					0.56	
	Focal Length	FL_x (cm)		#	6.0-12.0	-		12.00
		FL_y (cm)		#	10.00	-		10.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	130.06					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-32. **P4-1 Transducer - Triplex Mode**

Transducer Model: P4-1 Operating Mode: Triplex Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.22	(c)	-	1.03	3.14	1.93
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	1.75					
	W_o	(mW)		#	-		122.50	122.50
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				86.99		
	z_1	(cm)				1.99		
	z_{bp}	(cm)				1.99		
	z_{sp}	(cm)	4.22				4.96	
	$d_{eq}(z_{sp})$	(cm)					0.37	
	f_c	(MHz)	2.05	#	-	2.49	2.49	2.49
	Dim of A_{aprt}	X (cm)		#	-	1.41	1.41	1.41
		Y (cm)		#	-	1.40	1.40	1.40
Other Information	PD	(µsec)	0.89					
	PRF	(Hz)	420.00					
	pr@PIImax	(MPa)	2.15					
	deq@PIImax	(cm)					0.37	
	Focal Length	FL_x (cm)		#	-	6.00		6.00
		FL_y (cm)		#	-	10.00		10.00
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	130.06					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

***NOTE**: The following tables on the P10-4 transducer, are advanced information. The transducer will not be available for Customers until 1.8.* system / software release

Table 9-33. **P10-4 Transducer - B-Mode**

Transducer Model: P10-4 Operating Mode: B-Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.50	0.73	-	-	-	1.13
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.10					
	W_o	(mW)		26.32	-		-	26.52
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.47				-	
	$d_{eq}(z_{sp})$	(cm)					-	
	f_c	(MHz)	4.26	5.83	-	-	-	4.26
	Dim of A_{aprt}	X (cm)		0.48	-	-	-	0.48
		Y (cm)		0.56	-	-	-	0.56
Other Information	PD	(µsec)	0.85					
	PRF	(Hz)	1332.51					
	pr@PIImax	(MPa)	3.85					
	deq@PIImax	(cm)					-	
	Focal Length	FL_x (cm)		3.00	-	-		5.00
		FL_y (cm)		3.50	-	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	482.65					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-34. **P10-4 Transducer - M-Mode**

Transducer Model: P10-4 Operating Mode: M-Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS non-scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.42	0.23	0.38	-	0.50	0.79
Associated Acoustic Parameter	$p_{r.3}$	(MPa)	2.93					
	W_o	(mW)		18.44	18.44		18.44	18.44
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.47				1.60	
	$d_{eq}(z_{sp})$	(cm)					0.20	
	f_c	(MHz)	4.27	4.27-4.27	4.27-4.27	-	4.27	4.27-4.27
	Dim of A_{aprt}	X (cm)		0.48	0.48	-	0.48	0.48
		Y (cm)		0.56	0.56	-	0.56	0.56
Other Information	PD	(µsec)	0.85					
	PRF	(Hz)	568.48					
	pr@PIImax	(MPa)	3.51					
	deq@PIImax	(cm)					0.20	
	Focal Length	FL_x (cm)		5.00	5.00	-		5.00
		FL_y (cm)		3.50	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	427.60					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-35. **P10-4 Transducer - PW Mode**

Transducer Model: P10-4 Operating Mode: PW Mode

Index Label			MI	TIS scan	TIS non-scan $A_{aprt} \leq 1$	TIS scan $A_{aprt} > 1$	TIB non-scan	TIC
Global Maximum Index Value			1.43	(c)	1.20	-	2.20	1.87
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.21					
	W_o	(mW)		#	50.45		50.45	50.45
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	1.35				0.62	
	$d_{eq}(z_{sp})$	(cm)					0.42	
	f_c	(MHz)	5.04	#	4.99	-	4.99	4.99
	Dim of A_{aprt}	X (cm)		#	0.64	-	0.64	0.64
		Y (cm)		#	0.56	-	0.56	0.56
Other Information	PD	(µsec)	0.47					
	PRF	(Hz)	97.73					
	pr@PIImax	(MPa)	3.79					
	deq@PIImax	(cm)					0.23	
	Focal Length	FL_x (cm)		#	13.00	-		13.00
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	270.41					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-36. **P10-4 Transducer - Color Mode**

Transducer Model: P10-4 Operating Mode: COLOR Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-	scan	non-	
					$A_{aprt} \leq 1$	$A_{aprt} > 1$	scan	
Global Maximum Index Value			1.63	(c)	1.19	-	0.35	2.86
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.64					
	W_o	(mW)		#	49.61		12.61	49.61
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	0.62				0.74	
	$d_{eq}(z_{sp})$	(cm)					0.21	
	f_c	(MHz)	4.96	#	4.96-5.34	-	5.48	4.96-5.34
	Dim of A_{aprt}	X (cm)		#	0.48	-	0.24	0.48
		Y (cm)		#	0.56	-	0.56	0.56
Other Information	PD	(µsec)	3.44					
	PRF	(Hz)	675.00					
	pr@PIImax	(MPa)	4.05					
	deq@PIImax	(cm)					0.21	
	Focal Length	FL_x (cm)		#	5.0-10.0	-		5.0-10.0
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	425.48					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

The table below provides Track 3 reporting values for the specific operating modality, for the specific **z.one** transducer.

Table 9-37. **P10-4 Transducer - Triplex Mode**

Transducer Model: P10-4 Operating Mode: Triplex Mode

Index Label			MI	TIS			TIB	TIC
				scan	non-scan $A_{aprt}\leq 1$	scan $A_{aprt}>1$	non-scan	
Global Maximum Index Value			1.63	(c)	1.20	-	2.20	2.86
Assoc Acoustic Parameter	$p_{r.3}$	(MPa)	3.64					
	W_o	(mW)		#	50.45		50.45	49.61
	min of[$W_{.3}(z_1)$, $I_{TA.3}(z_1)$]	(mW)				-		
	z_1	(cm)				-		
	z_{bp}	(cm)				-		
	z_{sp}	(cm)	0.62				0.62	
	$d_{eq}(z_{sp})$	(cm)					0.42	
	f_c	(MHz)	4.96	#	4.99	-	4.99	4.96-5.34
	Dim of A_{aprt}	X (cm)		#	0.64	-	0.64	0.48
		Y (cm)		#	0.56	-	0.56	0.56
Other Information	PD	(µsec)	3.44					
	PRF	(Hz)	675.00					
	pr@PIImax	(MPa)	4.05					
	deq@PIImax	(cm)					0.23	
	Focal Length	FL_x (cm)		#	13.00	-		5.0-10.0
		FL_y (cm)		#	3.50	-		3.50
	$I_{PA.3}$ @MI_{max}	(W/cm^2)	425.48					
Operating Control Conditions	Control 1							
	Control 2							
	Control 3							
	Control n							

Notes:

(a) This index is not required for this operating **mode**; see section 4.1.3.1 of the **Output Display Standard**

(b) This probe is not intended for transcranial or neonatal cephalic uses.

(c) This formulation for TIS is less than that for an alternate formulation in this **mode**.

\# No data are reported for this **operating condition** since the **global maximum** index value is not reported for the reason listed.

Display Accuracy and Precision

The output display indices are calculated with the accuracy described below. Also listed is the precision of the displays. A discussion of the accuracy statements follows their specification.

Thermal Index Display Accuracy and Precision

It is estimated that 90% of TI values will be +/-45% of the displayed TI value or + 0.15% of the displayed value, whichever value is larger. This is approximately +/- 2 dB.

A displayed value of 0.0 for TI means that the calculated value is less than 0.05%.

Mechanical Index Display Accuracy and Precision

It is estimated that 90% of MI values will be within +/-25% of the displayed value, or + 0.15 of the displayed MI value, whichever value is larger. This is approximately +/- 2 dB.

The MI is displayed with a precision of 0.1.

Discussion of Display Accuracy

The stated display accuracy values are determined relative to the MI and TI models, equations, and measurement methods specified in the *"Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, Revision 2" (NEMA UD3).* The TI and MI are relative indicators for the likelihood of tissue thermal rise and mechanical bioeffects, respectively. The accuracy statements listed here are not bound on the deviation of the displayed indices from actual temperature rise or pressure levels in the body.

The TI and MI values are determined from measurements in water and derated for tissue attenuation using an assumed homogenous tissue model with attenuation of 0.3 dB/cm/MHz and the sound propagation properties of water. Most tissues attenuate ultrasound at a greater rate. Fluids such as amniotic fluid attenuate less. In addition, the propagation of ultrasound is a nonlinear one in most cases, to different degrees in water and various tissues, with varying resultant effects on actual MI or TI values. The MI is a relative indicator for the likelihood of a mechanical bioeffect, such as cavitation, and its model assumes the presence of nucleation sites needed for cavitation. The TI models assume a blood perfusion length of 1 cm. Tissue perfusion lengths and rates are dependent on vasculature and blood flow and the thermal properties of the surrounding tissue, which vary greatly. The bone TI derivation assumes all ultrasound energy is absorbed by the impinged bone.

The accuracy estimates stated are based on the variability in acoustic output of ZONARE probes and systems, uncertainties in measurements made per the AIUM / NEMA standards, and uncertainties or approximations introduced in implementing the MI and TI algorithms in **z.one** software. They are not based on errors in the AIUM / NEMA MI or TI models, errors introduced by the measurement standards, differences between actual tissue paths and properties and those of water, or the effects of nonlinear propagation on the measured values.

Measurement Precision and Uncertainty of Acoustic Output Values

The measurement precision of quantities are listed in the table below. They are measured as part of determining MI or TI values. Quantities are listed as one standard deviation, in percentage.

Table 9-38. **Measurement Acoustic Value Accuracy**

Parameter	Description	Precision	Uncertainty
Pulse Intensity Integral (PII)	Energy density (mJoules / cm^2) in an ultrasonic pressure wave. Used in TI, Ispta.0, and Ispta.3 determination.	10.0%	+20% -26%
Peak Rarefactional Pressure (Pr)	Largest pressure amplitude (MPa) of the negative pressure half-cycles in an ultrasonic pressure wave. Used in MI determination.	5.0%	+12% -13%
Acoustic Power (W)	Time-average acoustic power in an ultrasonic beam. Influenced by pressure wave amplitude and length, as well as pulse repetition frequency. Used in TI determination.	5.0%	+ / -10%
Center Frequency (Fc)	Center frequency (MHz) of an ultrasonic pressure wave. Used in TI and MI determination.	1.0%	+ / - 2%

Guidance Documents

- *Medical Ultrasound Safety, American Institute of Ultrasound in Medical (AIUM),* 1994.
- *"Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" (NEMA, UD 2).*
- *Acoustic Output Measurement and Labelling Standard for Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medical* (AIUM), January 1998.

- *Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment, American Institute of Ultrasound in Medicine,* National Electrical Manufacturers Association, 1998.

Product Labeling

Figure 8-1 through figure 8-10 depict the labeling that is required by various regulatory authorities, and describe their location.

Operational labelling (e.g. front panel controls, rear panel connectors) is explained in Chapter 2, "Getting Started."

Contact ZONARE if any of these labels are missing or damaged beyond legibility. The **z.one** labels herein are for reference only and are not shown to scale.

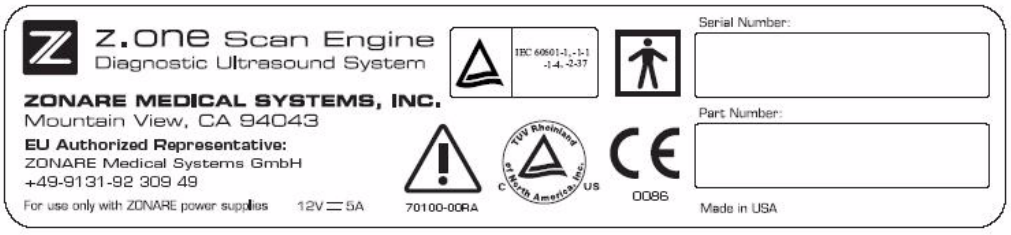


Figure 9-1. **The z.one Scan Engine- Model/Serial No. (with appropriate SN/PN entries)**

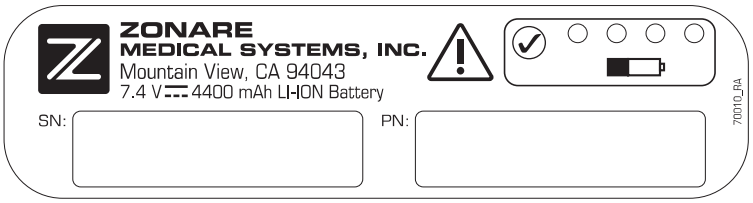


Figure 9-2. **z.one Battery - Model/Serial No. (with appropriate SN/PN entries)**

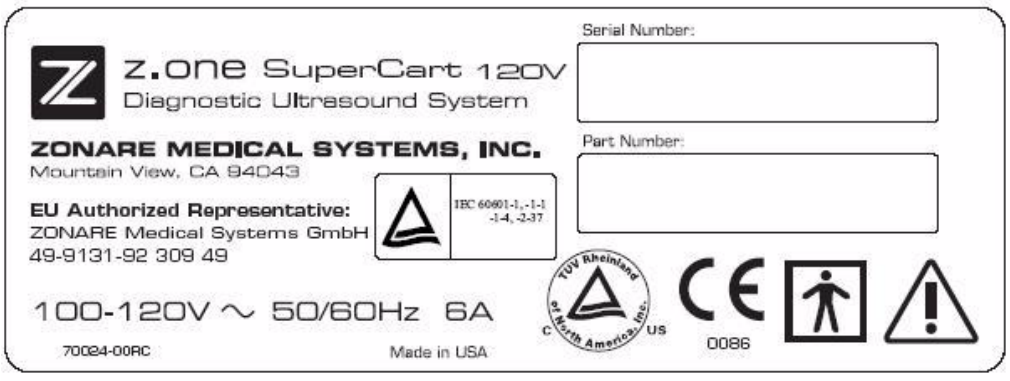


Figure 9-3. **100-120V SuperCart Rear Panel - Model/Serial No. (with appropriate SN/PN entries)**

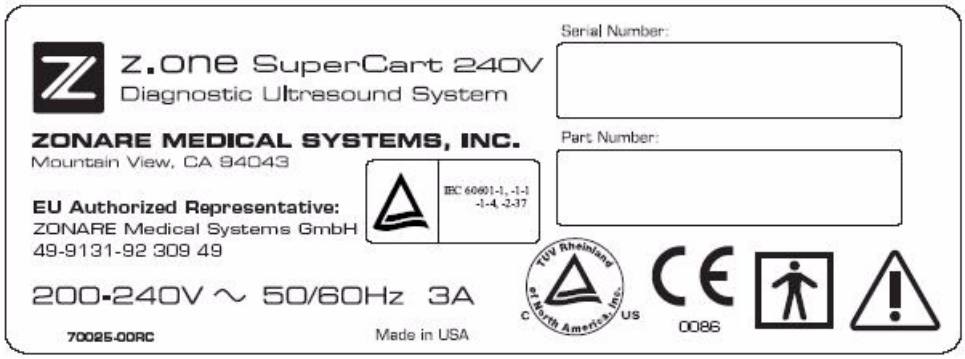


Figure 9-4. **200-240V SuperCart Rear Panel - Model/Serial No. (with appropriate SN/PN entries)**

Figure 9-5. **100-120V SuperCart Backpack Outlet Strip Label**

Figure 9-6. **200-240V SuperCart Backpack Outlet Strip Label**

Figure 9-7. ***mini*Cart Rear Panel - Model/Serial No. (with appropriate SN/PN entries)**

Figure 9-8. **Linear Array Transducer Labels (with appropriate SN/PN entries)**

Figure 9-9. **Curved Array Transducer Labels (with appropriate SN/PN entries)**

Figure 9-10. **EV Transducer Labels (with appropriate SN/PN entries)**

Figure 9-11. **Phased Transducer Labels (with appropriate SN/PN entries)**

Figure 9-12. **AC Power Adapter Label (with appropriate SN/PN entries)**

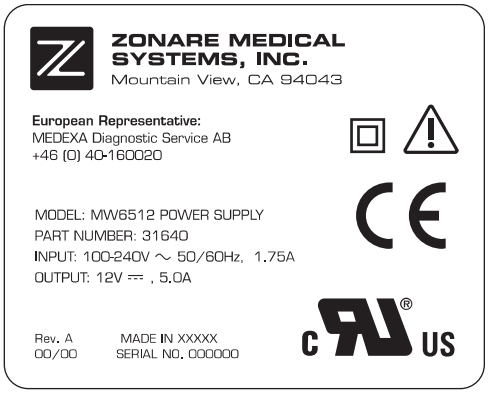


Figure 9-13. **AC Battery Adapter Power Supply Label**

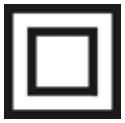
Alternating Current

Direct Current

V Voltage

Hz Cycles per second

Type BF (Body Model, Floating)



Class II Device

Attention-consult accompanying documents

10

User Maintenance

This chapter explains maintenance, care and service of your z.one which should be performed to maintain proper system operation.

These operations include:

- Touchscreen calibration (on the Scan Engine)
- Backing-up and restoring of user Presets & System Settings
- Performing a software upgrade procedure on the Scan Engine
- Main AC fuse replacement on the miniCart.
- System Care

WARNING: Shock hazards exist if the AC power connection for the SuperCart, *mini*Cart, or AC Adapter are not properly grounded. Equipment must be connected to a "hospital grade" receptacle. Do not remove the grounding wire.

The **z.one** enclosures contain no operator-serviceable components. To avoid electrical shock, do not remove covers. As with any other electrical equipment, always use care when operating this instrument. Refer servicing to Tech Support only. Failure to do so may void your warranty or service contract coverage.

To safely use and maintain the **z.one**, ensure the following:

- To avoid electrical shock, always disconnect the AC power before cleaning any part of the **z.one**.

- Do not immerse the transducer past the cleaning / disinfection level depth specified in the Transducer Care section. Do not immerse the transducer for longer than specified cleaning / disinfecting time. Do not use any transducer that has been immersed beyond the specified maximum immersion depth, or has been soaked longer than specified time.
- This battery has a safe-smart device. Do not disassemble or alter the battery.
- Charge the battery at room temperature.
- Do not short-circuit battery by directly connecting the positive and negative terminals with metal objects.
- Do not heat or discard the battery in a fire.
- Do not expose the battery to temperatures above 120°F (50°C).
- Do not charge the battery near a heat source.
- Do not leave the battery in direct sunlight.
- Recharge the battery only with a SuperCart, *mini*Cart, or Zonare battery charger.
- Do not use a damaged battery.
- Inspect the battery for damage before charging or placing the battery in the Scan Engine.
- Do not connect the battery to an electrical power outlet.

CAUTION: Do not excessively twist or bend the cables; this may cause failure.

- Improper cleaning or disinfection of any part of the **z.one** may cause permanent damage. Follow the cleaning and disinfection instructions.
- Do not submerge the transducer past the indicated immersion point.
- Do not use solvents or abrasives to clean any part of the **z.one**.
- Do not spill liquid on the **z.one**.
- Do not immerse the battery in water or allow it to get wet.
- Do not put the battery into a microwave oven or pressurized container.
- Use only ZONARE batteries.
- Store the battery between 32° and 120°F (0° and 50°C).
- If the battery leaks, emits odors, emits heat, or is deformed or discolored in any way, immediately remove it from the **z.one** and stop using the battery.

Touchscreen Calibration (Scan Engine)

The touchscreen function on the LCD display of the **z.one** Scan Engine rarely requires calibration. Normally the only time touchscreen calibration is required, is immediately following a complete main system software re-installation on the Scan Engine.

Touchscreen Calibration Procedure

1. For a SuperCart based **z.one**, undock the Scan Engine from the SuperCart, press the release lever to flip open the LCD display for viewing.
2. Remove the touchscreen stylus from its storage area, in the groove on the top-right edge of the plastic display cover on the Scan Engine.
3. Power on the Scan Engine and allow it to fully boot.
4. Using the Tab key, tab to the **Tools** tab.
5. Using the Menu Control, highlight **System Setup** and press the **Select** key to activate
6. Using the Menu Control, highlight the **Touchscreen** selection from the menu, and press the **Select** key to begin the touchscreen calibration process.

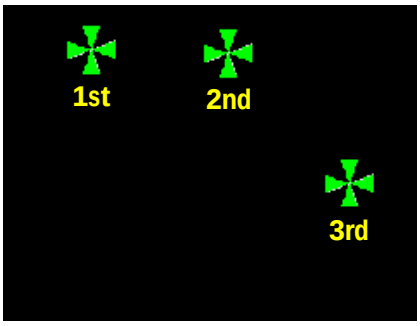


Figure 10-1. **Touchscreen Calibration Screen**

7. Place the tip of the stylus in the center of the first green target crosshair that appears on the display, and lightly press-and-hold until the crosshair moves to second location.
8. Repeat the press-and-hold of the stylus, in the center of the 2nd green target crosshair that now appears on the display.
9. Repeat the process one more time, for the 3rd (and final) green target crosshair.

NOTE: It is important that the stylus be held stationary (not bounced), with a single contact point made (and held) in the center of the green crosshair, during the touchscreen calibration process. Failure to do so may result in the calibration process returning a "*User failed to calibrate the touchscreen, please retry*" error message. If this happens, repeat the touchscreen calibration procedure, while observing this required stylus contact technique.

User Diagnostic Panel Menu: Operations

Introduction

The User Diagnostic Panel screen allows access to important system information and product support processes. The basic page of the User Diagnostic Panel allows access to following functions:

- "Checking of system software revision level
- "Checking Scan Engine serial number
- "Checking revision levels of major PC boards in z.one
- "Capturing of system status to a "LOG" file (to USB Memory Stick)
- "Capturing current image screen, and storing as a.BMP file (to USB Memory Stick)
- "Sending the contents of the LOG directory on USB Memory Stick (via an internet connection) to ZONARE
- "Checking for availability of software upgrades from remote ZONARE site
- "Remote (over the internet) software upgrade of the **z.one** from the ZONARE site

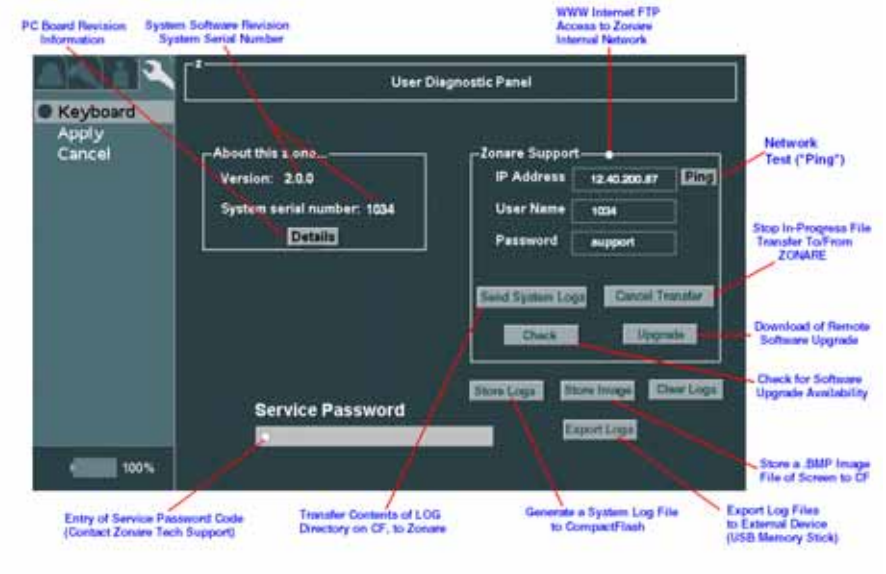


Figure 10-2. **User Diagnostic Panel**

To access the User Diagnostic Panel

1. Using the "Tab" button and Menu Control on the Scan Engine (or SuperCart) user interface, advance to the "Tools" menu and then sequence through the following selection:

   Tools tab --> System Setup --> Diagnostics

The majority of the functions offered in the User Diagnostic Panel (sending system logs, sending images, downloading / upgrading of system software) involve the use of an internet connection between the **z.one** and Zonare's network server for the purpose of uploading or downloading of files. Performing any of these procedures will require contacting Zonare Technical Support to receive specific information on IP address, and log-in used to make the connection.

PRESETS - SYSTEM: Backup/Restore

The **z.one** has two different categories of customized parameter sets that can be created from customer-specific settings that are configured into the **z.one** by the Operator. These two categories are:

- **PRESETS**
- **SYSTEM**

The **Presets** category consists of customized image setup parameters (depth, frequency, etc.) that can be created for each transducer, for each mode of

operation. These customized user presets allow for a one-time setup of commonly used configurations and control settings by the Operator.

The **System** category of configurable settings includes parameters such as institution name, date/time, DICOM settings, function key assignments, etc.

In order to protect these customized parameter sets, it is critically important that the Operator save them on a regular basis (whenever changes have been made), to a USB Memory Stick. This saved USB Memory Stick can then be used to instantly restore the **z.one** to its complete previous operating configuration, in the case of a post-software upgrade, or Scan Engine replacement.

Backing-Up System/Presets

To ***backup*** the SYSTEM and (user) PRESETS, to USB Memory Stick, perform the following procedures.

PRESET Backup

1. Power on the **z.one** and allow it to fully boot.
2. Insert the Presets/System backup USB Memory Stick into the USB port at the rear of the **z.one**
3. Using the Tab key, tab to the **Tools** tab
4. Using the Menu Control, highlight **Preset Admin** and press the **Select** key to activate
5. Using the Menu Control, highlight **Backup Presets**, and press the **Select** key to initiate the storage of user presets to the USB Memory Stick
6. When the System setup parameters have been restored, the z.one will automatically reboot

SYSTEM Backup

1. Power on the **z.one** and allow it to fully boot.
2. Insert the Presets/System backup USB Memory Stick into the USB port at the rear of the **z.one**
3. Using the Tab key, tab to the **Tools** tab
4. Using the Menu Control, highlight **Preset Admin** and press the **Select** key to activate
5. Using the Menu Control, highlight **Backup System**, and press the **Select** key to initiate the storage of system settings to the USB Memory Stick

Restoring System/Presets

To ***restore*** the SYSTEM and PRESETS, from the USB Memory Stick on which they were previously stored, perform the following procedures.

PRESET Restore

1. Power on the **z.one** and allow it to fully boot.
2. Install the USB Memory Stick containing the previously backed up User **Presets** into port at the rear of the **z.one**
3. Using the Tab key, tab to the **Tools** tab
4. Using the Menu Control, highlight **Preset Admin** and press the **Select** key to activate
5. Using the Menu Control, highlight **Restore Presets**, and press the **Select** key to initiate the retrieval of User Presets from the USB Memory Stick

SYSTEM Restore

1. Power on the **z.one** and allow it to fully boot.
2. Install the USB Memory Stick containing the previously backed up **System** setup parameters into port at the rear of the **z.one**
3. Using the Tab key, tab to the **Tools** tab
4. Using the Menu Control, highlight **Preset Admin** and press the **Select** key to activate

5. Using the Menu Control, highlight **Restore System**, and press the **Select** key to initiate the retrieval of the System setup parameters from the USB Memory Stick

Software Upgrade/Installation

Periodically, ZONARE will release new software for your system. This upgrade procedure is a very easy-to-perform operation that can be done by the Operator. Total installation time is approximately 15 minutes.

The method for accessing system software upgrades for installation at a User site, is directly dependent upon the network and computer equipment present at the site. The different software upgrade accessibility options are:

Best (fastest) Option:

– Direct FTP download (over the internet,) of system software to an installed USB Memory Stick, via a network connection on the **z.one**

2nd Best Option:

– Local laptop / PC FTP site download (over the internet) of system software, to a locally installed USB Memory Stick

Basic (slowest) Option:

– Ground shipment of USB Memory Stick, pre-loaded with system software installer files, to the Customer site

To check on the latest software revision level that is currently available, please contact ZONARE Technical Support:

- "1-877-913-9663 (USA and Canada)
- "1-650-316-3199

Verifying Current System Software Revision

1. Using the "**Tab**" button and Menu Control on the Scan Engine (or SuperCart) user interface, advance to the "**Tools**" menu and then sequence through the following selection:

   Tools tab --> **System Setup** --> **Diagnostics**

2. The software revision will be displayed in the top left corner of the Diagnostic page.

System Software Installation Procedure

NOTE: It is recommended that the Scan Engine be operated in ***standalone*** mode (undocked from the SuperCart) during the software upgrade/installation procedure. It is extremely important to ensure that the battery pack in the Scan Engine have a minimum of 50% charge capacity, PRIOR to beginning this software upgrade procedure.

CAUTION: If the battery charge is too low, either replace the existing battery with a properly charged one, or dock the Scan Engine in the SuperCart (with power applied to the SuperCart) for approximately 1 hour (to recharge the battery to an adequate standalone use level), prior to starting this procedure.

NOTE: The Scan Engine may also be connected to the AC Power Pack.

1. Verify that the Scan Engine is initially powered off.
2. Disconnect the transducer from the Scan Engine, if currently attached.
3. Un-dock (remove) the Scan Engine from the SuperCart (software installations should be performed with the Scan Engine in standalone mode).
4. Press the green power button (at the left rear of the Scan Engine) to power on the unit.

Figure 10-3. **Power on the Scan Engine**

5. Allow the Scan Engine to complete a normal boot (start) operation (approximately 25 seconds).
6. Open the rear access door on the Scan Engine and insert the USB Memory Stick fully into the USB connector, pressing lightly to ensure that it is seated.

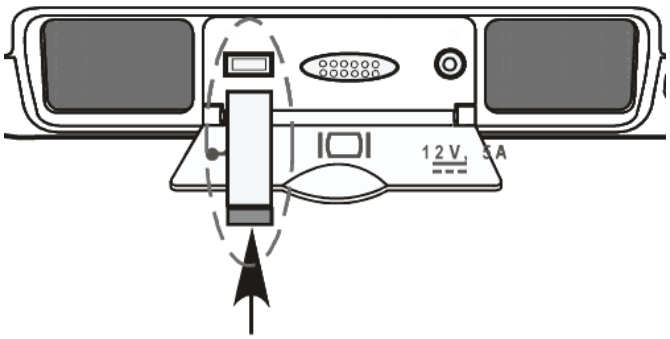


Figure 10-4. **Insert USB Memory Stick**

7. A dialog box will display on the LCD Display screen.

8. To accept the installation offer, and begin the software installation process, press the **Select** button on the user interface of the Scan Engine for each of the two (2) dialog boxes that are sequentially displayed.

NOTE: If it is determined that the software revision of the USB Memory Stick is the same as the current version in the Scan Engine and you want to cancel (select **No**) the install operation (or you want to cancel for any other reason), press the **Back** key, and then manually remove the USB Memory Stick.

9. The software install process is as follows:
   - System license verification
   - Software file transfer (download)
   - Software validation

NOTE: The complete software downloading sequence will take approximately 10 minutes.

10. At the completion of a successful software installation process, a dialog box displays on the LCD Display screen, instructing the user to remove the USB Memory Stick, and press any key to reboot the Scan Engine.

11. Remove the USB Memory Stick card from the Scan Engine.

12. Press any key on the system, and it will reboot and begin normal operation.

Main AC Power Fuse Replacement (*mini*Cart)

Over-current protection for AC power on the **z.one** *mini*Cart is provided by two in-line fuses. These fuses are externally accessible for easy replacement by the Operator, without the need for any special tools or equipment. The following procedure describes the steps required for fuse replacement.

1. Power off the Scan Engine.
2. Completely disconnect the main AC power cord from the rear of the *mini*Cart, to ensure no AC power is being applied to the **z.one**.
3. The fuse holder is located directly above the connector (at the lower-left, rear of the *mini*Cart) where the main AC power cord plugs into the back of the *mini*Cart.
4. Using a small screwdriver (or the edge of a fingernail, if applicable), lift up on the plastic release tab (shown by the arrow below), in the slot at the bottom-center of the fuse holder's cover plate.

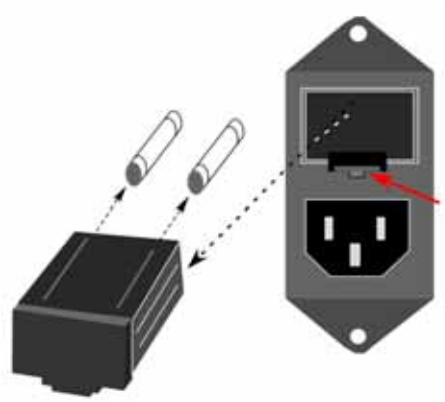


Figure 10-5. ***mini*Cart Main AC Fuse Replacement**

5. Slide the fuse holder assembly out of its receptacle.
6. Remove both fuses from the fuse holder, and inspect.
7. Replace fuses as required, and reverse above steps for re-installation.

Fuse Specifications: - 100-120V Systems: **T3.15A/250V**

- 200-240V Systems: **T6.3A/250V**

Basic System Care

Checking the Battery

The Scan Engine contains a rechargeable battery. The charge on this battery is automatically maintained if the Scan Engine is left docked in the pocket of the SuperCart between uses, and the SuperCart remains connected to an active power receptacle, with the circuit breaker (located at the rear of the SuperCart) in the "On" position. This procedure explains how to maintain proper operation of the battery.

To check the battery

1. To verify that the battery is in a ready condition, first ensure that the **z.one** SuperCart has been connected to an active power receptacle for at least 4 hours (with the Scan Engine docked in the SuperCart) without the Scan Engine in use.
2. Remove the Scan Engine from the SuperCart. If a transducer is installed, remove it and store it properly.
3. Press the **Power** button on the Scan Engine, and then immediately make note of the battery charge indicator LED indicators. All 4 battery LED indicators are lit when the battery is fully charged. The 4 LED indicators are illuminated in 25% increments:
   - 4 LEDs=76-100% charge
   - 3 LEDs= 51-75% charge
   - 2 LEDs=26-50% charge
   - 1 LED=0-25% charge
4. If you are certain that the battery was fully charged (as explained above) and the Scan Engine does not perform accordingly, replace the battery or contact Tech Support for assistance. There are no user remedies for battery insufficiency problems other than maintaining a full charge, as explained earlier.

Battery Charging

For optimum **z.one** performance the battery packs should be maintained in a charged state. Battery charging occurs when the SuperCart is connected to an active power receptacle, the battery pack is inserted into the Scan Engine, and the Scan Engine is stored in a docked condition within the SuperCart.

Remote charging, and recalibrating (resetting of the charge fuel gauge) of the battery pack is done using the Zonare 2-Bay Battery Charger unit (Part # Z311: for 110V or #Z312: for 220V). Refer to for more information on remote battery charging.

Battery Maintenance

The battery is a spill-proof maintenance-free sealed battery. There are no user actions for battery maintenance, other than maintaining a charged state.

CAUTION: If the **z.one** will be stored in a location where power cannot be supplied (to maintain the battery in a charged state) for more than five days, the battery should be removed from the Scan Engine to help prevent potentially hazardous conditions as a result of the battery deteriorating.

Typical battery life is one to two years when the battery is maintained in a charged state. Leaving the battery in an uncharged state reduces its life. Utilizing the Zonare 2-Bay Battery Charger's "Recalibrate" (*recondition*) cycle, on a scheduled basis, will help maintain optimum efficiency and performance of the batteries.

WARNING: To protect the **z.one** battery from potential thermal damage, the system monitors the temperature of the battery at all times. If the battery is detected as exceeding the maximum safe operating temperature, a warning message will appear on the display of the **z.one**.

The Operator should immediately complete all active operations, in preparation for the system automatically initiating a power-down sequence.

Internal CompactFlash Maintenance

The **z.one** internal CompactFlash (CF) should not be used for long-term storage of studies and patient information. As part of normal User maintenance on the **z.one**, previously processed studies should be deleted from the internal CF on a regular basis (daily or weekly).

A "Low Storage" warning will appear when "Free" storage falls below a minimum threshold. When you see this warning, immediately export studies to a permanent storage media (USB Memory Stick), and then delete those studies from the internal CompactFlash.

If "Free" storage reaches zero, the system will automatically create space by deleting the oldest study.

Cleaning the z.one

13” LCD Display Cleaning (SuperCart & *mini*Cart)

WARNING: Take care not to damage or scratch the glass or LCD panel.

Do not apply pressure on the glass or LCD panel.

Do not apply or spray liquid directly to the glass, panel or cabinet as excess liquid may cause damage to internal electronics. Apply the liquid to the cleaning cloth.

WARNING: Do NOT use any of the following

- Lye or cleaning solutions containing lye*
- Acid
- Detergents with fluoride
- Detergents with ammonia
- Detergents with abrasives
- Steel wool
- Sponge with abrasives
- Cloth with thread made of steel
- Other coarse tools

Cleaning the Front Glass:

1. Prior to cleaning, turn off the AC circuit breaker on the SuperCart (or unplug the *mini*Cart from the AC power outlet), to remove all power from the unit
2. Clean the glass using a soft cotton cloth, lightly moistened with a watery solution or a mild commercial glass-cleaning product suited for coated glass surfaces
3. Wipe dry with a clean, dry, soft, lint-free cloth

Cleaning the External Case:

1. Prior to cleaning, turn off the AC circuit breaker on the SuperCart (or unplug the *mini*Cart from the AC power outlet), to remove all power from the unit

2. Clean the external case of the display using a soft cotton cloth, lightly moistened with a mild cleaning product recognized for safe use on medical equipment
3. Repeat with water only
4. Wipe dry with a clean, dry, soft cloth

WARNING: Do NOT expose the external case of the LCD display to any of the following agents:

- Cidex
- Betadine
- Alcohol (Isopropyl and Ethyl)
- Ammonia based cleaners (Windex)
- Aquasonic Gel

General z.one Exterior Surface Cleaning

1. Do not use disinfectants (such as gluteraldahyde or hydrogen peroxide), or acetone, to clean any surfaces on the **z.one**, or its accessories.
2. Prior to cleaning, turn off the AC circuit breaker on the SuperCart (or unplug the *mini*Cart from the AC power outlet), to remove all power from the unit, and remove the battery from the Scan Engine.
3. Wipe the **z.one** surfaces with a safe disinfectant solution NOT mentioned in the previous step, following the disinfectant label instructions for use.
4. Do not autoclave, immerse, or attempt to sterilize the LCD display or transducers.
5. Do not spill or spray liquid directly on the control panel, LCD display, battery charger, AC power adapter, or transducer connector.
6. Using soap and water or a mild disinfectant, gently wipe the surfaces of the **z.one** with a moistened cloth.
7. After each use, remove and dispose of any use cover/sheath. Wipe off any excess gel from the transducer and clean it properly.
8. Air-dry the **z.one**.

WARNING: To avoid electrical shock prior to cleaning the **z.one,** turn off the AC circuit breaker at the rear of the SuperCart (or unplug the *mini*Cart from the AC power outlet), and remove the battery from the Scan Engine. Always use protective eyewear and clothing when cleaning or disinfecting the **z.one**.

9. The level of disinfection required for the **z.one** is dictated by the type of tissue in the **z.one** contact usage. Ensure that the disinfectant type is appropriate for the type of transducer and application.

10. If premixed disinfection solution is used, observe the solution expiration date to ensure that the solution has not expired.

CAUTION: Do not allow the disinfectant to contact metal surfaces. Use a soft cloth and warm soapy water to remove any disinfectant that remains on metal surfaces.

Transducer Maintenance

Regularly check transducers for signs of wear or damage.

Inspecting transducers

Routinely inspect your transducers for the following problems.

1. Inspect each transducer for signs of wear or damage
   - "Cracks in case or transducer face
   - "Cuts or gouges on any part of the transducer, including transducer face, case, cable, and connector
   - "Buckling or bulging of the lens material on the transducer face
   - "Damage to the transducer connector

2. If problems found, order a replacement transducer

WARNING: Immediately replace a transducer that exhibits any of the above damage symptoms.

Verifying Imaging Performance

Routinely verify transducers for proper imaging performance.

1. Scan yourself or a tissue-equivalent phantom which each transducer.
2. Verify uniform image quality. Look for signs of drop-out (dark columns in the image area).

Cleaning and Care of Transducers

There are two methods of cleaning and disinfection available for the **z.one** transducers.

- For external-use transducers (CLA and LA), ZONARE recommends cleaning the transducers using the “wipe method” (described next) after each exam. In addition, ZONARE recommends disinfecting these transducers, using the “immersion method”, on a weekly basis.
- For internal probe (EV), ZONARE recommends performing the “immersion method” disinfection after each exam, and the use of a soft brush for ensuring thorough cleaning of all surfaces and crevices of the Biopsy Mounting Features on the EV handle.

The **z.one** transducers cannot be sterilized. When sterility is required, use a sterile transducer cover/sheath and sterile ultrasound/coupling transducer gel. Follow all prescribed sterility techniques.

WARNING: To avoid electrical shock, prior to cleaning any transducer, fully disconnect it from the Scan Engine. If cleaning of the transducer is being performed near the **z.one**, ZONARE also recommends disconnecting the AC power from the SuperCart.

CAUTION: Always use protective eyewear and clothing when cleaning or disinfecting the transducers.

CAUTION: Do not allow the disinfectant to come in contact with metal surfaces (transducer connector). Use a soft cloth and warm soapy water to remove any disinfectant that remains on metal surfaces.

CAUTION: When a brush is used for cleaning of transducers (in the case of the EV probe) ONLY a “soft” brush should be used, as coarse/stiff-bristle brushes may cause transducer damage.

Cleaning and Disinfecting

Cleaning: Wipe Method

1. Disconnect the transducer from the **z.one**.
2. Remove the transducer cover/sheath and discard.
3. For initial cleaning of the surface of the transducer, use a soft cloth dampened with a mild soap (Liquinox) and water solution to remove particulate, ultrasound coupling gel, or body fluids.

4. As a second phase of cleaning, use a diluted bleach solution (1/4 cup bleach per 1 gallon of clean water) on a soft cloth. Apply the cleaning solution to the cloth, and then use to wipe down the transducer.
5. After cleaning, wipe the transducer again with a soft cloth soaked with fresh water, to remove any residual cleaning solution prior to use on patients.
6. Air dry the transducer or towel dry it with a clean cloth.
7. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact Tech Support.

Disinfecting: Immersion Method

CAUTION: During immersion disinfection, never immerse the transducers longer than 45 minutes. Damage may occur to the transducer housing and/or components if disinfection times exceed these recommended limits.

CAUTION: Using a nonrecommended cleaning or disinfectant solution, incorrect solution strength, or immersing the transducer deeper or longer than indicated can damage the transducer.

CAUTION: To prevent possible damage to the electronics of the transducer, never immerse the transducer beyond the point (10mm below the top edge of the transducer housing) shown in Figure 10-6, "Immersion Level Limits," on page 10-19.

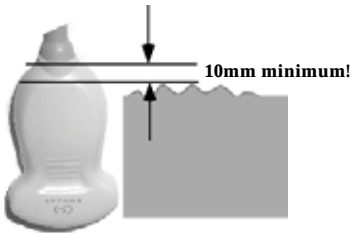


Figure 10-6. **Immersion Level Limits**

1. Disconnect the transducer from the **z.one**.
2. Remove the transducer cover/sheath and discard.
3. For initial cleaning of the surface of the transducer, use a soft cloth dampened with a mild soap (Liquinox) and water solution to remove particulate, ultrasound coupling gel, or body fluids.

4. Mix the disinfectant solution (refer to Table 10-1, "Currently Zonare Approved Transducer Disinfectants," on page 10-20), according to the manufacturer's "Recommendations For Use" instructions (found on the container) for solution strengths.

5. Immerse the transducer into the disinfecting solution, ensuring it is not immersed below the depth indicated in the figure (refer to Figure 10-6, "Immersion Level Limits," on page 10-19).

6. Immersion time should be within the following limits:

- Minimum: Not less than 15 minutes
- Maximum: NOT to exceed 45 minutes

7. As a first phase of post-disinfection cleaning, wipe the surface of the transducer, with a soft cloth dampened a mild soap (Liquinox) and water solution.

8. As a second phase of post-disinfection cleaning, use a diluted bleach solution (1/4 cup bleach per 1 gallon of clean water) on a soft cloth. Apply the cleaning solution to the cloth, and then use to wipe down the transducer.

NOTE: For the EV probe, use a soft brush for thorough cleaning of all surfaces and crevices of the Biopsy Mounting Features on the EV handle

9. As a final phase of post-disinfection cleaning, wipe the transducer again with a soft cloth soaked with fresh water, to remove any residual cleaning solution prior to use on patients.

10. Air dry (or towel dry) the transducer with a soft, clean cloth.

11. Examine the transducer for damage, such as cracks, splitting, holes, or fluid leaks. If damage is evident, discontinue use of the transducer and contact Tech Support.

Table 10-1. **Currently Zonare Approved Transducer Disinfectants**

Transducers	Disinfectant Type
C5–2	Cidex (only)
L10–5, L8-3	Cidex (only)
EV9–4	Cidex (only)
P10-4, P4-1	Cidex (only)

System Mechanical & Visual Inspection

Verifying System Display

1. Verify the display is securely mounted to the system.
2. Turn display left and then right. Verify display moves freely in both directions.
3. Tilt display up and then down. Verify display moves freely in both directions.

Verifying System Controls

1. Hold the release button. Raise and lower the system control panel.
2. Verify the control panel moves up, down and locks when button released.
3. If control panel drifts after releasing the button, an adjustment of the control cable may be required. Contact Technical Support.

Verifying Wheel & Brake Operation

1. Check the wheels and wheel brake for damage.
2. Verify brake operation. Engage brake paddle by pressing it down. The two front wheels should lock in position. Pressing the brake paddle a second time should release them.
3. If the brake fails to work correctly, contact Technical Support for assistance.

Verifying Cable & Peripheral Connectivity

With all system power disconnected, verify the following:

1. Check the AC power cord for damage or excessive wear.
2. Verify peripherals are securely attached.
3. Verify peripheral cabling is properly connected.
4. If defects found, correct or replace defective item.

System Functionality

Verifying System Controls

1. Verify operation and backlighting of all control panel buttons.
2. If a button fails to light, contact Technical Support for ordering replacement part.

Verifying System Operation

1. Power on the system.
2. Verify the system completes the boot sequence and the monitor displays the image screen within 30 seconds.
3. Record the system software version on the Maintenance Checklist.
4. Verify the system recognizes all transducers when connected.
5. Verify the trackball functions smoothly.
6. Check the operation of B-mode, M-mode, and C-mode.
7. Check the operation of Doppler mode. Invert the waveform and verify that sound is audible from both speakers.

Verifying Peripherals

B/W Printer

1. Acquire the desired ultrasound image on the **z.one**.
2. Press the "FREEZE" key on the **z.one**, to obtain a static image.
3. Press the "PRINT" button to trigger a print of the current on-screen image to the UP-897MD.
4. If print quality is less than optimal, clean the print head and test again.
5. If necessary, adjust printer settings with the operator. Reference printer manual for more instructions on settings

Color Printer

1. Acquire the desired ultrasound image on the **z.one**.
2. Press the "FREEZE" key on the **z.one**, to obtain a static image.
3. Press the "PRINT" button to trigger a print of the current on-screen image to the UP-21MD.
4. If necessary, adjust printer settings with the operator. Reference printer manual for more instructions on settings.

DVD Recorder

Recording

1. Power on the LQ-MD800, and insert a blank DVD-R- into the unit.
2. To setup a video recording session, while scanning a patient on the **z.one**, place the LQ-MD800 into the record mode by using the controls on the unit.
3. To start recording, press the **F1** key () on the SuperCart, to un-pause the LQ-MD800.

NOTE: **F1** key must be pre-programmed in the **System Setup**->**Function Keys** menu, to the "**Ext Sync**" selection.

Finalizing (Burning) DVD For Viewing

NOTE: Prior to a DVD-R being ready for playback (viewing) use, the content must be permanently burned into the DVD-R. This process is called "Finalizing", and is performed on the LQ-MD800 by executing the following steps.

1. Using the **Ext Video** key on the SuperCart, enable video output from the DVD recorder to be displayed on the SuperCart's Barco LCD monitor.
2. Press **Shift** & **Menu** on LQ-MD800 player.
3. Go to the Disk Information screen, using the arrow keys (menu displays on **z.one** monitor).
4. Choose the **Finalize** selection from the menu.

NOTE: The **Finalize** process can take up to 14 minutes to complete. The required time is inversely proportion to the amount of recorded data on the DVD-R.

5. The DVD-R can now be removed from the LQ-MD800, and played (viewed) by inserting it into the DVD reader on any PC or similar device.

Shipping and Storage

The environmental conditions required for shipping and/or storage are not the same as for normal operation. Refer to Chapter 11,

To prevent fire or shock hazard, do not expose the **z.one** to moisture or rain. If it is necessary to transport the **z.one** through precipitation, place a protective cover over it. If moisture gets into the **z.one**, allow the **z.one** to dry thoroughly before plugging the power cord into an electrical outlet.

Do not expose the **z.one** to extremely high temperatures because damage may result. Avoid storing the **z.one** in a hot environment. Refer to Chapter 11, for allowable operating and storage environmental information.

Avoid sudden changes in temperature because condensation can form on the internal parts of the **z.one**. If the **z.one** has been moved between environments with extremes of temperature and / or humidity, allow the **z.one** to rest for at least 30 minutes in a controlled environment before using. Refer to Chapter 11, for acceptable storage and operating temperatures.

Handle and transport the **z.one** gently. Do not expose it to rough movements or vibrations, which may result in damage to the **z.one**.

When the SuperCart or *mini*Cart is not in use, be certain to leave the power cord connected to an active power receptacle (and the circuit breaker turned "on" (up) for the SuperCart) to keep the batteries in the Scan Engine charged.

Disposal

The **z.one** contains lead solder on the circuitry and storage batteries. Follow applicable hospital and / or local regulations to dispose of batteries and electronics properly. No special precautions need to be taken except those that are usual for disposal of electrical and electronic equipment of this type.

For instructions on proper disposal methods for the following consumable items, refer to the directions for use packaged with them.

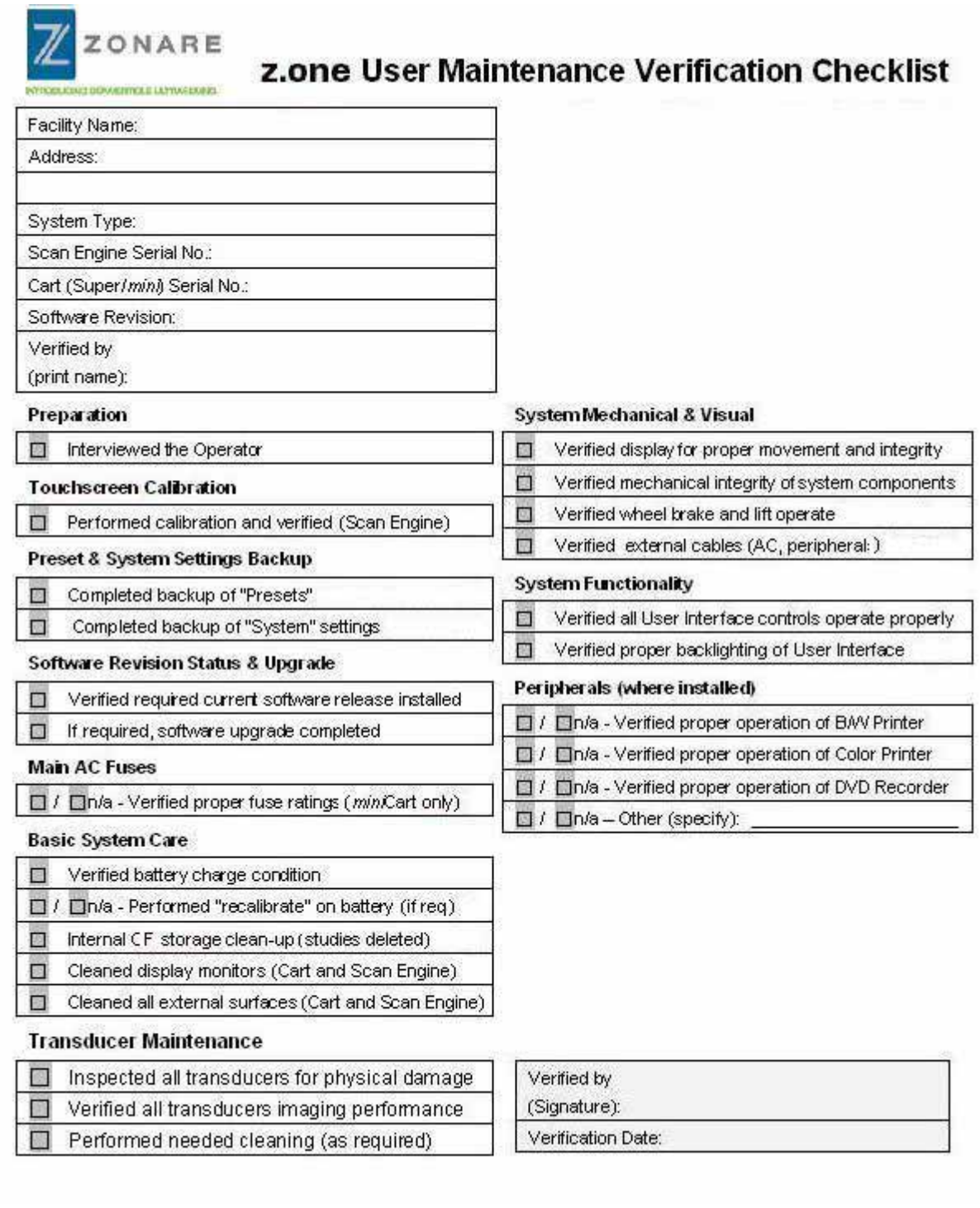
Transducer Covers

WARNING: Transducer covers may be contaminated and must be handled accordingly.

Batteries

WARNING: Do not heat or discard batteries in a fire.

z.one User Maintenance Verification Checklist



ZONARE

z.one User Maintenance Verification Checklist

Facility Name:
Address:
System Type:
Scan Engine Serial No.:
Cart (Super/*mini*) Serial No.:
Software Revision:
Verified by (print name):

Preparation

☐ Interviewed the Operator

Touchscreen Calibration

☐ Performed calibration and verified (Scan Engine)

Preset & System Settings Backup

☐ Completed backup of "Presets"
☐ Completed backup of "System" settings

Software Revision Status & Upgrade

☐ Verified required current software release installed
☐ If required, software upgrade completed

Main AC Fuses

☐ / ☐n/a - Verified proper fuse ratings (*mini*Cart only)

Basic System Care

☐ Verified battery charge condition
☐ / ☐n/a - Performed "recalibrate" on battery (if req)
☐ Internal CF storage clean-up (studies deleted)
☐ Cleaned display monitors (Cart and Scan Engine)
☐ Cleaned all external surfaces (Cart and Scan Engine)

Transducer Maintenance

☐ Inspected all transducers for physical damage
☐ Verified all transducers imaging performance
☐ Performed needed cleaning (as required)

System Mechanical & Visual

☐ Verified display for proper movement and integrity
☐ Verified mechanical integrity of system components
☐ Verified wheel brake and lift operate
☐ Verified external cables (AC, peripheral:)

System Functionality

☐ Verified all User Interface controls operate properly
☐ Verified proper backlighting of User Interface

Peripherals (where installed)

☐ / ☐n/a - Verified proper operation of B/W Printer
☐ / ☐n/a - Verified proper operation of Color Printer
☐ / ☐n/a - Verified proper operation of DVD Recorder
☐ / ☐n/a – Other (specify): _____

Verified by (Signature):
Verification Date:

11

Troubleshooting

Contact Information for ZONARE Service and Technical Support

United States and Canada

ZONARE Medical Systems Inc.
1061 Terra Bella Avenue
Mountain View, CA 94043-1839

Toll-free live-voice support	877-913-9663 or 650-316-3199
Tech Support fax line	650-230-2817
Tech Support by e-mail	techsupport@zonare.com
Sales Support by e-mail	salessupport@zonare.com
Web site	www.zonare.com

Europe and Asia

Contact your local authorized dealer or use the contact information above. Toll-free live-voice support is not available outside the United States.

User Troubleshooting Procedures

Many **z.one** malfunctions are caused by a routine problem, such as power disconnection or the maladjustment of basic imaging or peripheral device (LCD display) controls. Before calling Zonare Tech Support, please perform the following troubleshooting procedures on the affected component(s). Do not remove any of the system covers. Only controls and other hardware located on the outside of the system or that are accessible through the rear access door are user serviceable. Trained ZONARE service personnel should be the only people to attend to problems that require access to the system's internal electronic devices.

Power-On Problems

SuperCart (with docked Scan Engine) fails to power on

- Ensure that the AC power is connected to a wall outlet.
- Ensure that the circuit breaker (located in the lower-left of the rear panel) is in the "on" (up) position.
- Ensure that the "scanner link" indicator lamp (bottom green indicator) (located on the right-hand side of the Rear I/O panel at the back of the SuperCart) is flashing after the Scan Engine has been docked (prior to powering on the Scan Engine).
- If the LED is not flashing, remove (undock) the Scan Engine from the SuperCart pocket and inspect for any damage to Scan Engine and SuperCart docking connectors; check for any debris/obstructions in the pocket or connectors.
- Re-dock the Scan Engine into the SuperCart pocket, ensuring proper alignment, and then repeat the power-on procedure.
- If the SuperCart still does not power on, remove the Scan Engine and attempt to operate in the standalone mode to determine if the problem is with the SuperCart or the Scan Engine.
- If either component fails to start-up after these steps, contact Zonare Tech Support.

Scan Engine (undocked) fails to power on

- Remove the battery from the Scan Engine, and then press the battery charge status button to ensure that a charge of greater than 25% is available. If the battery charge is insufficient, replace the battery or dock the Scan Engine in a powered-on SuperCart and allow time to recharge the battery.
- Disconnect the transducer from the Scan Engine (if attached), and then repeat the attempt at powering on the unit.

- Dock the Scan Engine in the SuperCart and attempt to power on the **z.one**. If the **z.one** powers on, the problem is in the Scan Engine battery. Replace the battery.
- If the Scan Engine still fails to power on, contact Zonare Tech Support.

System Start-Up Problems

Scan Engine (undocked) fails to properly boot

- Press the Power button on the Scan Engine, to begin the system boot operation.
- Immediately (within 5 seconds) press the **RETURN** button, to interrupt the normal boot operation and bring up the special options menu.
- Press the **PRINT** button, to add the ***Compact Flash Boot*** selection to the special options menu.
- Install a System Software (bootable) USB Memory Stick into the USB connector at the rear of the Scan Engine.
- Press the **F1** button to initiate a ***Compact Flash Boot*** operation.
- If the Scan Engine still fails to complete the boot operation, contact Zonare Tech Support.
- If the Scan Engine boots properly, proceed to perform a system software re-installation process, from the system software Flash Memory Stick.

Peripheral Problems

Peripheral(s) fails to power on

- Check the AC power cord connections at the AC power outlet box (located inside backpack storage area) at the rear of the SuperCart.
- Ensure that the green power indicator light on the AC power outlet box is illuminated, indicating that power is present.
- Temporarily connect the AC power cord of the peripheral to a local AC receptacle, and test for operation of the peripheral.
- If the peripheral fails to power on after these steps, contact Zonare Tech Support.

Color or B/W printer fails to print

- Check that the printer has paper available.

- Ensure that the video and control cables are properly connected at the rear I/O panel on the SuperCart, and on the printer device.
- Check the "Audio/Video" settings (accessed via the system menus, through the path: **TOOLS** | **SYSTEM SETUP** | **AUDIO/VIDEO**) on the Scan Engine, and then ensure that the proper video format (NTSC/PAL) is selected.
- If the printer fails to print after these steps, contact Zonare Tech Support.

Transducer Problems

Transducer not recognized by system (no B-mode imaging)

- To ensure a positive connection, disconnect the transducer and reconnect it.
- To determine a problem with the transducer or system, attach a different transducer to the Scan Engine.
- Disconnect the transducer. Power down the Scan Engine. Power the Scan Engine back on, and reinsert the transducer to test for functionality.
- Remove the Scan Engine from the SuperCart, and repeat the transducer removal/installation process.
- If system still fails to operate any transducers, contact Zonare Tech Support.

Imaging Problems

No/poor B-mode image

- Ensure that the brightness and/or contrast controls on the LCD display have not been altered from proper settings.

NOTE: To ensure the quality of the grayscale resolution of the LCD display, use the grayscale test pattern (via the Diagnostic menu) that is available on the SuperCart. Ensure that all shades can be visualized, making small adjustments to brightness and contrast from factory defaults, as required, to see all intensities.

- Adjust the B-mode **gain** control.
- In the on-screen menu, adjust the **A Output** (acoustic power) level.
- In the on-screen menu, under the **Preset** tab, select one of the factory default settings (General, etc.) to determine possible maladjustment of user presets.
- Ensure an adequate supply of acoustic coupling gel and good patient/transducer contact.

- Switch to a different transducer to determine the problem.

No/poor Color Mode image or PW Doppler

- Ensure that the brightness and / or contrast controls on the LCD display have not been altered from proper settings.

NOTE: To ensure the quality of the grayscale resolution of the LCD display, use the grayscale test pattern (via the Diagnostic menu) that is available on the SuperCart. Ensure that all shades can be visualized, making small adjustments to brightness and contrast from factory defaults, as required, to see all intensities.

- Make adjustments to the various Doppler controls (**gain, filter, scale**) to attempt to resolve problem.
- Ensure that the scanning angle between the transducer face and the direction of blood flow is optimized.
- In the on-screen menu, under the **Preset** tab, select one of the factory default settings (General, etc.) to determine possible maladjustment of user presets.
- Ensure that there is an adequate supply of acoustic coupling gel and good patient / transducer contact.
- Switch to a different transducer to determine the problem.

General Operation Problems

Function (F1-F4) key(s) do not operate

- Using the on-screen menu, follow the path: **TOOLS** | **SYSTEM SETUP** | **FUNCTION KEYS**) to access the menu for the user configuration of the assignments of the function keys.

NOTE: The function keys on the SuperCart (F1-F4) can be configured independently from the function keys on the standalone Scan Engine (F1-F2).

Unable to modify existing User Preset (shown as *grayed out* on screen)

- Ensure that the desired user preset has been previously (prior to attempting to modify it) selected as the active preset.

Unable to access any of the DICOM configuration menus (shown as *grayed out* on screen)

- Verify this system was purchased with the “DICOM Option” enabled.
- Verify license file (Z-ONE.dat) file contained on software installer USB Memory Stick, used during last software installation, is current.

- Reinstall software on Scan Engine, and test for DICOM functionality at completion.
- Call Zonare Tech Support if problem continues.

12 Specifications

This chapter provides electrical, connection, physical, environmental, and authorized accessory specifications.

This chapter also contains the EMC / CE mark compliance information.

Refer to "z.one Measurement Accuracy" on page 5-30 and "Acoustic Output" on page 9-9 for related specifications.

Table 12-1. **Specifications - (SuperCart w/Scan Engine)**

Type	Parameter	Value
Electrical	Power requirements (120V system)	100-120VAC, 50-60Hz, 6A max
	Power requirements (220V system)	200-240VAC 50-60Hz, 3A max
	Power consumption (no peripherals) (max.)	180W - (625 BTU / Hr)
	Power consumption (w / peripherals) (max.)	720W - (2450 BTU / Hr)
Environmental (operating)	Cooling requirements	See power consumption above.
	Ambient air temperature	0-35°C (32-95°F)
	Ambient humidity	15-80%, non-condensing
	Ambient pressure	700-1060 hPa
Environmental (storage)	Storage air temperature	-20-60°C (-4-140°F)
	Storage humidity	15-90%, non-condensing
	Ambient humidity	15-80%, non-condensing
	Ambient pressure	500-1060 hPa

Table 12-1. **Specifications - (SuperCart w/Scan Engine)**

Type	Parameter	Value
Physical (weight)	SuperCart – (operating)	84 kg (185 lb.)
	SuperCart – (Shipping weight)	102 kg (225lb.)
	Scan Engine – (w / battery)	5.6 lb (2.5 kg)
	Scan Engine – (shipping weight)	8 lb (3.6 kg)
Physical (dimensions)	SuperCart - height, max operational	141 cm (55.6 in)
	SuperCart - height, min operational	129 cm (50.6 in)
	SuperCart - height, display lowered for transport	104 cm (41.1 in.)
	SuperCart - width	61 cm (24.2 in.)
	SuperCart - depth	85 cm (33.6 in.)
	Scan Engine - height	7.3 cm (2.9 in)
	Scan Engine - width	18.7 cm (7.4 in)
	Scan Engine - depth	25 cm (9.8 in)
I / O connectors	VGA output	15 pin (RGB analog: 0.7V p-p, 75 ohm) (Video out digital: TTL levels)
	S-Video output	MiniDIN-4 (chroma: NTSC 0.286V p-p, 75 ohm; PAL 0.3V p-p, 75 ohm) (luma: 1V p-p, 7 5 ohm)
	S-Video input	MiniDIN-4 (chroma: NTSC 0.286V p-p, 75 ohm; PAL 0.3V p-p, 75 ohm) (luma: 1V p-p, 7 5ohm)
	Composite video output	RCA jack (1V p-p, 75 ohm)
	Composite video input	RCA jack (1V p-p, 75 ohm)
	Audio output (left / right)	RCA jack (5V p-p, 100 ohm output impedance)
	Audio input (left / right)	RCA jack (4V p-p, 25K ohm input impedance)
	Ethernet (port)	RJ-45 – 10 / 100BaseT
	Remote expose	3.5mm mono jack (open drain drive through 150 ohm, 10 mA max)
**not active*	**USB 2.0 Host*	*USB-Type A (VBUS 5.0V, 1A max)*
**not active*	**Parallel printer*	*DB25 (0-5.0V signals)*

Table 12-1. **Specifications - (SuperCart w/Scan Engine)**

Type	Parameter	Value
	Serial – RS-232 – DTE (male)	DB9 (RS-232 standard)
	Serial – RS-232 – DCE (female)	DB9 (RS-232 standard)

Table 12-2. **Specifications - (*mini*Cart w/Scan Engine)**

Type	Parameter	Value
Electrical	Power requirements (120V system)	100-120VAC, 50-60Hz, 6A max
	Power requirements (220V system)	220-240VAC 50-60Hz, 3A max
	Power consumption (no peripherals) (max.)	120W - (408 BTU / Hr)
	Power consumption (w / peripherals) (max.)	420W - (1428 BTU / Hr)
Environmental (operating)	Cooling requirements	See power consumption above.
	Ambient air temperature	0-35^{o}C (32-95^{o}F)
	Ambient humidity	15-80%, non-condensing
	Ambient pressure	700-1060 hPa
Environmental (storage)	Storage air temperature	-20-60^{o}C (-4-140^{o}F)
	Storage humidity	15-90%, non-condensing
	Ambient humidity	15-80%, non-condensing
	Ambient pressure	500-1060 hPa
Physical (weight)	*mini*Cart – (operating)	55 kg (132 lbs.)
	*mini*Cart – (Shipping weight)	68 kg (150 lbs.)
	Scan Engine – (w / battery)	5.6 lb (2.5 kg)
	Scan Engine – (shipping weight)	8 lb (3.6 kg)
Physical (dimensions)	*mini*Cart - height, max operational	160 cm (63 in)
	*mini*Cart - height, min operational	134 cm (53 in)
	*mini*Cart - height, display lowered for transport	104 cm (41.1 in.)
	*mini*Cart - width	57.2 cm (22.5 in.)

Table 12-2. **Specifications - (*mini*Cart w/Scan Engine)**

Type	Parameter	Value
	*mini*Cart - depth	56.1 cm (22.0 in.)
	Scan Engine - height	7.3 cm (2.9 in)
	Scan Engine - width	18.7 cm (7.4 in)
	Scan Engine - depth	25 cm (9.8 in)
I/O connectors	USB 2.0 Host	USB-Type A (VBUS 5.0V,0 .5A max)

EMC Standards Compliance

CIS PR11:98, IEC

Electro-Medical Compliance

The **z.one** has been designed, manufactured, and tested to comply with the following internationally recognized standards.

IEC 60601-1: 2000

Medical electrical equipment part 1: General requirements for safety.

IEC 60601-1-1: 2003

Medical electrical equipment part 1: General requirements for safety. Collateral standard: Safety requirements for medical electrical.

IEC 60601-1-2: 2001

Medical electrical equipment part 1-2: General requirements for safety. Collateral standard: Electromagnetic compatibility - Requirements and tests.

The **z.one** has been tested and certified, as listed in Table 12-3.

Table 12-3. **IEC 60601-1-2: 2001 Certification**

CISPR 11 – RF emissions	Group 1, Class A The **z.one** is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
IEC 61000-3-2 harmonic emissions	Class A

Table 12-3. **IEC 60601-1-2: 2001 Certification**

IEC 61000-3-3 voltage fluctuations / flicker emissions	Complies
IEC 61000-4-2 electrostatic discharge (ESD)	Compliance level: ±6 kV contact ±8 kV air *Electromagnetic environment guidance*: Floors should be wood, concrete, or ceramic tile. If floors are covered with a synthetic material, the relative humidity should be at least 30%.
IEC 61000-4-4 electrical fast transients (EFT)	Compliance level: ±2 kV for power supply lines ±1 kV for I / O lines *Electromagnetic environment guidance*: Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-5 surge	Compliance level: ±1 kV differential mode ±2 kV common mode *Electromagnetic environment guidance*: Main power quality should be that of a typical commercial or hospital environment.
IEC 61000-4-11 voltage dips, short interruptions and voltage variations on power supply input lines	*Electromagnetic environment guidance*: Main power quality should be that of a typical commercial or hospital environment. If the **z.one** requires continued operation during main AC power interruptions, it is recommended that the **z.one** be powered from an uninterrupted power supply.
IEC 61000-4-8 power frequency (50 / 60 Hz) magnetic field	Compliance level: 3A / m *Electromagnetic environment guidance*: Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

IEC 60601-1-4 edition 1.1

Medical electrical equipment – part 1-4: General requirements for safety.

Collateral standard: Programmable electrical medical systems.

IEC 60601-2-37:200 + A1:2004 + A2:2005

Medical electrical equipment – part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.

A

Glossary

This appendix contains both a glossary and a list of acronyms used in this manual. If you have other questions, call Tech Support. Refer to "Contact Information for ZONARE Service and Technical Support" on page 11-1.

Glossary

This glossary includes an alphabetic listing of terms. The American Institute of Ultrasound in Medicine (AIUM) has published, *Recommended Ultrasound Terminology, Second Edition*, 1997. Refer to it for ultrasound terms not contained in this glossary.

Terms

ALARA — As Low As Reasonably Achievable: The guiding principle of ultrasound use, which states that you should keep patient exposure to ultrasound energy as low as reasonably achievable for diagnostic results.

B-mode — Brightness Mode: A way to display echoes of tissue structures in the body, in a two dimensional format on a video display. Video pixels are assigned a brightness level based on echo signal amplitude.

Clip Store — A time sequence (3 seconds - 2 minutes) of live image frames that are captured and stored to internal CompactFlash and / or DICOM storage device, for post-study review capability.

Color Mode — A Doppler imaging mode used to visualize the presence, velocity, and direction of blood flow in a wide range of flow states.

Curved array transducer — Identified by the letter C (curved) and a pair of numbers (5-2). The numbers corresponds to the optimum frequency bandwidth expressed in MHz. The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam.

DDP Data Display Box: The DDP is a reserved space in the bottom-right corner of the image area (on the LCD Display) in which information is displayed about depth of measurement cursor, velocity, and other assorted calculation values.

DICOM Digital Imaging and Communication in Medicine: An industry standard used for the storage and printing of digital imaging data files across a wide spectrum of disciplines in the medical field.

Dual Imaging feature allowing simultaneous display of two different images on the screen, operating in different modalities (i.e. Color Flow and Power Doppler)

FDA Food and Drug Administration: A government agency responsible for ensuring safety to humans in the use of products produced or sold / used in the United States of America.

Harmonics Harmonic imaging: An imaging feature that can be selected on the **z.one,** which transmits at one frequency and receives at a higher harmonic frequency to reduce noise and clutter and improve resolution.

JPEG Joint Photographic Experts Group: The original name of the committee that wrote the JPEFG image file standard, that is designed for compressing either full-color or gray-scale images.

Linear array transducer Identified by the letter L (linear) and a pair of numbers (10-5). The numbers corresponds to the optimum frequency bandwidth expressed in MHz.The transducer elements are electrically configured to control the characteristics and direction of the acoustic beam (e.g., L38).

M-mode Motion Mode: A way to show the motional behavior of cardiac structures (valves, heart wall, etc.). A single beam of ultrasound is transmitted and reflected signals are displayed as dots of varying intensities in a time axis display.

MI Mechanical Index: An indication of the likelihood of mechanical bio effects occurring. The higher the MI value, the greater the likelihood of mechanical bio effects.

MPPS Modality Performed Procedure Step: An advanced DICOM service function. MPPS consists of a network connection between the **z.one** and a HIS / RIS management system. The MPPS service allows for defining specific imaging sequences (steps) to be performed on the patient, and transfer of resultant images and data, based upon a specific clinical modality.

NTSC National Television Standards Committee: A video standard format setting used in the United States, and a number of other countries worldwide. See also PAL.

PAL Phase Alternating Line: A video standard format setting used in a number of different countries worldwide. See also NTSC.

Power Doppler A Doppler imaging mode, displayed in a 2D format, using color to visualize the presence and volume of blood flow in a wide range of flow states.

PRF Pulse Repetition Frequency: A measurement of the rate at which ultrasound transmit beams are triggered and sent into the body, in the various operating modalities (PW, Color, B-Scan).

PW Pulsed Wave mode: A Doppler recording of blood flow velocities in a range specific area along the length of the beam.

Retrospective Retrospective imaging: A functional operation on the **z.one** where pre-processed image data (from internal Cine memory) is recalled, with the capability to perform extensive image processing (gain, etc.) that is normally reserved only for live images on most other manufacturers ultrasound systems

ROI Region Of Interest: In Color mode, the targeted area within the B-mode image where acquisition of blood flow information will be targeted. The size, shape and location of this area is selected by the user, and delineated on the display by a green graphical border overlay.

RLE Run-Length Encoding: An industry standard protocol used for compressing of color and black-white image files, to reduce their size for minimizing storage requirements and / or maximizing file transfer rates.

Skinline A location within the B-mode image, on the display, that corresponds to the skin / transducer interface.

TI Thermal Index: The ratio of total acoustic power to the acoustic power required to raise tissue temperature by 1°C under defined assumptions.

TIB Thermal Index in Bone: Thermal index where the ultrasound beam passes through soft tissue and a focal region in the immediate vicinity of bone.

TIC Thermal Index in Cranial bone: Thermal index where the ultrasound beam passes through bone (in the skull) at the entrance to the body.

TIS Thermal Index in Soft tissue: Thermal index where the ultrasound beam passes through bone at the entrance to the body

Transducer Often commonly referred to as a “probe.” A device that transforms mechanical energy to electrical energy (during transmit cycle), and vice-versa (during the receive cycle). Ultrasound transducers contain piezoelectric elements, which when excited electrically, emit acoustic energy. When the acoustic energy is transmitted into the body, it travels until it encounters an interface or change in tissue properties. At the interface, an echo is formed that returns to the transducer, where this acoustic energy is transformed into electrical energy, processed, and displayed as anatomical information.

VKB Virtual Keyboard: On the standalone Scan Engine, a graphical representation of a normal alphanumeric keyboard is displayed (when required) for entering

text information. A stylus is used on the touchscreen display to make virtual keyboard entries.

z.one The ZONARE trademarked name for its full-featured convertible ultrasound product.

Acronyms

Table A-1. **Acronyms**

Acronym	Description
2D	Two Dimensional
AC	Abdominal Circumference (physical); Alternating Current (electronics)
AIUM	American Institute of Ultrasound in Medicine
ALARA	As Low as Reasonably Achievable
AE	Application Entity
B-mode	Brightness Mode
BPD	Biparietal Diameter
BX	Biopsy
CCA	Common Carotid Artery
CD	Color Doppler
CRL	Crown Rump Length
CRT	Cathode Ray Tube
dB	Decibel
DDB	Data Display Box
DICOM	Digital Imaging and Communications in Medicine
Dist	Distal
E / A	Left ventricle (E) / atrial kick (A)
ECA	External Carotid Artery
ECG	Electrocardiogram
EMC	Electro Mechanical Compliance
EMI	Electro Magnetic Interference
ESD	Electro Static Discharge
EV	Endo-Vaginal
Fc	Center Frequency
FL	Femur Length
GS	Gestational Sac
GYN	Gynecology
HR	Heart-Rate
ICA	Internal Carotid Artery
LCD	Liquid Crystal Display
MDD	Medical Device Directive
MI	Mechanical Index
M-Mode	Motion Mode

Table A-1. **Acronyms**

Acronym	Description
MPPS	Modality Performed Procedure Step
NEMA	National Electrical Manufacturers Association
NTSC	National Television Standards Committee
OB	Obstetrics
P	Pressure
PAL	Phase Altering Line
PD	Pulse Duration (dynamic) Power Doppler (operating mode)
PI	Pulsitility Index
PII	Pulse Intensity Integral
Pr	Peak Rarefactional Pressure
PRF	Pulse Repetition Frequency
Prx	Proximal
PW	Pulsed Wave
RI	Resistive Index
ROI	Region of Interest
S / D	Systolic / Diastolic
SV	Doppler Sample Volume
TGC	Time Gain Compensation
TI	Thermal Index
TIB	Bone Thermal Index
TIC	Cranial Thermal Index
TIS	Soft Tissue Thermal Index
TV	Transvaginal
V	Voltage
VKB	Virtual KeyBoard